

United States  
**Environmental Protection Agency**  
 Washington, DC 20460

☐ **Registration**  
☐ **Amendment**  
☒ **Other**

OPP Identifier  
 Number

**Application for Pesticide – Section I**

1. Company/Product Number EPA File Symbol 524-LOL	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	PM # 92	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section – II**

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.


**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010

**Section – III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	<input type="checkbox"/> Glass	
			No. per Container	<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other	
				(Specify)	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

**Section – IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Dr. Russell P. Schneider	Title Senior Director, Regulatory Affairs and Policy	Telephone No. (Include Area Code) (202) 393-2866
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Manager	
4. Typed Name J. Austin Burns Ph.D. Tel. (314) 694-6514	5. Date March 18, 2011	

Please read instructions on reverse before completing form.  
 EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95  
 White - EPA File Copy (original) Yellow - Applicant Copy



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.  
WASHINGTON, D.C. 20460

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## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	EPA Registration Number / File Symbol: 524-LOL
Active Ingredient(s) and/or representative test compound(s): <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7	Date: March 18, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 x TC1507 x MON 88017 x DAS-59122-7

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]  
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## Section III: CERTIFICATION


I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date 3-18-2011	Typed or Printed Name and Title J. Austin Burns Regulatory Affairs Manager
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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**DATA MATRIX**

Date: March 18, 2011	EPA Reg. No./File Symbol: 524-LOL	Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7
Ingredients: <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010		Monsanto Company	OWN	This Application
	Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010		Monsanto Company	OWN	Additional Supporting IRM Information

Signature 	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date March 18, 2011
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EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: February 14, 2011	EPA Reg. No./File Symbol: 524-LOL	Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	
Ingredients: <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Additional Supporting IRM Information

Signature 	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date March 18, 2011
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EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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MONSANTO



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 1, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

RUSSELL P. SCHNEIDER  
MONSANTO COMPANY  
1300 I STREET, NW, SUITE 450 EAST  
WASHINGTON, DC 20005-

PRODUCT NAME: MON 89034 X TC1507 X MON 88017 X DAS-59122-7  
COMPANY NAME: MONSANTO COMPANY  
OPP IDENTIFICATION NUMBER:  
EPA FILE SYMBOL: 524-LOL  
EPA RECEIPT DATE: 02/16/11

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 92, at (703) 308-8269.

Sincerely,

*P. L. Moore*

Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division

## Fee for Service

{890647D~

This package includes the following

☐ New Registration

☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☒ BPPD

☐ RD

Risk Mgr.

92

Receipt No.

S-

890647

EPA File Symbol/Reg. No.

524-LOL

Pin-Punch Date:

2/16/2011

☒ This item is NOT subject to FFS action.

### Action Code:

\*Requested:

Granted:

Amount Due: \$ ~~5789~~

### Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:

*J. Reilly*

Date:

*2/22/11*

Remarks:


\* Did not state category, but indicated on their appl. form

this was a protocol review.

Changed to NON-PRIA per Sheri Reilly's email of 2/28/11 (copy attached)

*T. O'Connell*  
2/28/11



Re: Fw: RESPONSE REQUIRED BY 3/2/11: Proof of PRIA fee payment  
required for protocol review (EPA file symbol 524-LOL)   
Sheryl Reilly to: Teresa Downs

02/28/2011 04:19 PM

Teresa,

We did ask for this protocol, so it should not be a PRIA submission.

I apologize for any confusion this has caused.

Sheryl

Sheryl K. Reilly, Ph.D.  
Chief, Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs (7511P)  
U.S. Environmental Protection Agency  
reilly.sheryl@epa.gov  
703-308-8269 (phone)  
703-308-7026 (fax)  
Visit <http://www.epa.gov/pesticides>

Teresa Downs

Good morning, Sheryl, Please see Russ Schnei...

02/28/2011 06:59:27 AM

From: Teresa Downs/DC/USEPA/US  
To: Sheryl Reilly/DC/USEPA/US@EPA  
Cc: "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>  
Date: 02/28/2011 06:59 AM  
Subject: Fw: RESPONSE REQUIRED BY 3/2/11: Proof of PRIA fee payment required for protocol review  
(EPA file symbol 524-LOL)

Good morning, Sheryl,

Please see Russ Schneider's email below concerning the protocol that you coded last week. Please let me know if you need to see this action; I have it on my desk.

Teresa Downs  
Information Services Branch  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
phone: (703)305-5363  
fax: (703)305-7670  
[www.epa.gov/pesticides](http://www.epa.gov/pesticides)

----- Forwarded by Teresa Downs/DC/USEPA/US on 02/28/2011 06:56 AM -----

From: "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>  
To: Teresa Downs/DC/USEPA/US@EPA  
Cc: "JENKINS, DANIEL J [AG/1920]" <daniel.j.jenkins@monsanto.com>  
Date: 02/24/2011 03:50 PM  
Subject: RE: RESPONSE REQUIRED BY 3/2/11: Proof of PRIA fee payment required for protocol review  
(EPA file symbol 524-LOL)

Teresa,

Per my voice mail, the protocol we sent to the Biopesticide and Pollution Prevention Division was not for their review, but a response to their request for a protocol that Monsanto uses to certify manufacturing facilities. There should be no fee or PRIA action assigned to this information as it was requested by BPPD as a FYI.

Thanks, and please let me know of your decision.

Russ

Dr. Russell P. Schneider  
Senior Director, Regulatory Affairs and Policy  
Monsanto Company  
1300 I St., NW  
Suite 450 East  
Washington, DC 20005  
202/383-2866

-----Original Message-----

From: Downs.Teresa@epamail.epa.gov [mailto:Downs.Teresa@epamail.epa.gov]  
Sent: Thursday, February 24, 2011 3:13 PM  
To: SCHNEIDER, RUSSELL P [AG/1920]  
Subject: RESPONSE REQUIRED BY 3/2/11: Proof of PRIA fee payment required for protocol review (EPA file symbol 524-LOL)

Dear Dr. Schneider:

The Biopesticide Division's PRIA team has identified the above action as subject to action code B902. Please email me a pay.gov receipt or a copy of a check in the amount of \$5,789 as proof of fee payment.

Section 33(B)[2(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Renewal Act, provides that the fee is due upon submission of the application. We received this action on 2/16/11. If proof of fee payment is not received by COB on 3/2/11, then we will reject this action for non-payment of the PRIA fee and send you an invoice for \$1,448. The Agency is required to collect a minimum of 25% of the applicable fee even if an application is rejected. If you do not pay the invoice by the date specified therein, then the fees will be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

If you have questions about the assignment of the above action code, please contact Sheryl Reilly at reilly.sheryl@epa.gov or (703)308-8269.

Sincerely,

Teresa Downs  
Information Services Branch  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
phone: (703)305-5363  
fax: (703)305-7670  
www.epa.gov/pesticides

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**RESPONSE REQUIRED BY 3/2/11: Proof of PRIA fee payment required for  
protocol review (EPA file symbol 524-LOL)**

Teresa Downs to: SCHNEIDER, RUSSELL P [AG/1920]

02/24/2011 03:12 PM

Dear Dr. Schneider:

The Biopesticide Division's PRIA team has identified the above action as subject to action code B902. Please email me a pay.gov receipt or a copy of a check in the amount of \$5,789 as proof of fee payment.

Section 33(B)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Renewal Act, provides that the fee is due upon submission of the application. We received this action on 2/16/11. If proof of fee payment is not received by COB on 3/2/11, then we will reject this action for non-payment of the PRIA fee and send you an invoice for \$1,448. The Agency is required to collect a minimum of 25% of the applicable fee even if an application is rejected. If you do not pay the invoice by the date specified therein, then the fees will be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

If you have questions about the assignment of the above action code, please contact Sheryl Reilly at [reilly.sheryl@epa.gov](mailto:reilly.sheryl@epa.gov) or (703)308-8269.

Sincerely,

Teresa Downs  
Information Services Branch  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
phone: (703)305-5363  
fax: (703)305-7670  
[www.epa.gov/pesticides](http://www.epa.gov/pesticides)

Released  
~~ON HOLD~~

**Pending receipt of certification of PRIA fee payment**

Date placed on hold: 2/24/11

Date released: 3/1/11

Receipt: S- 890647

File Symbol/Reg. #: 524-L0L

**Registrant contact information:**

Name: Russ Schneider

Phone #/Email address: russell.p.schneider@monsanto.com

Notes: No fee payment  
2/24/11 Sent email

Information Services Branch point of contact: Teresa Downs, S-6922, (703)305-5363

United States  
**Environmental Protection Agency**  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier  
Number

**Application for Pesticide – Section I**

1. Company/Product Number EPA File Symbol 524-LOL	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	PM # 92	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section – II**

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.


**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

**Section – III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other			

**Section – IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Dr. Russell P. Schneider		Title Sr. Director for Regulatory Affairs & Policy		Telephone No. (include Area Code) (202) 383-2866	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Affairs Manager			
4. Typed Name J. Austin Burns Ph.D. Tel. (314) 694-6514		5. Date February 14, 2011			

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95  
EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy



**MONSANTO COMPANY**  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63167  
<http://www.monsanto.com>

**Attn:** Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

**Subject:** Additional information regarding the manufacturing process and refuge assurance program for a 5% seed mix refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

Dear Dr. Reilly:

Thank you and your team for the opportunity to review our proposed manufacturing processes for a 5% seed mix refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 on February 3, 2011. As requested by Mike Mendelsohn, accompanying this letter is an additional document describing the Monsanto licensee seed conditioner's qualification for seed mix refuge products. This document, in addition to the submission on January 28, 2011 clarifying Monsanto's manufacturing process and standards, addressing both Monsanto-owned and licensee operated facilities should help clarify Monsanto's Refuge Assurance Program for seed mix refuge products (RIB).

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

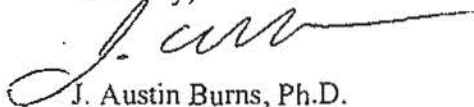
- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	A
Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	A
48384001 Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	B

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,



J. Austin Burns, Ph.D.  
Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD  
Dr. Alan Reynolds, EPA BPPD  
Dr. Russell P. Schneider, Monsanto Company

## LIST OF SUBMITTED DOCUMENTS

### Administrative Materials

Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

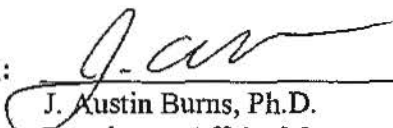
MRID Number \_\_\_\_\_

### EPA Requested Information

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

MRID Number \_\_\_\_\_

Company Official:

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
(314) 694-6514

Date

2-14-2011

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.  
Senior Director, Regulatory Affairs and Policy  
(202) 383-2866



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.  
WASHINGTON, D.C. 20460

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	EPA Registration Number / File Symbol: 524-LOL
Active Ingredient(s) and/or representative test compound(s): <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7	Date: February 14, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 x TC1507 x MON 88017 x DAS-59122-7

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**Section I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**Section II: GENERAL OFFER TO PAY**

☐ (Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)  
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**Section III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date 2-14-2011	Typed or Printed Name and Title J. Austin Burris Regulatory Affairs Manager
---------------	-------------------	---



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

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## DATA MATRIX

Date: February 14, 2011

EPA Reg. No./File Symbol: 524-LOL

Page 1 of 1

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 × TC1507 × MON 88017  
× DAS-59122-7

Ingredients: *Bacillus thuringiensis* CryIA.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Company	OWN	This Application
	Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature

Name and Title

J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date

February 14, 2011

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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## DATA MATRIX

Date: February 14, 2011  
EPA Reg. No./File Symbol: 524-LOL Page 1 of 1  
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167  
Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7  
Ingredients: *Bacillus thuringiensis* CryIA.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature:   
Name and Title: J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
Date: February 14, 2011

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MONSANTO  
im ine



February 14, 2011

Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63167  
<http://www.monsanto.com>

**Attn:** Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

**Subject:** Additional information regarding the manufacturing process and refuge assurance program for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

Dear Dr. Reilly:

Thank you and your team for the opportunity to review our proposed manufacturing processes for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on February 3, 2011. As requested by Mike Mendelsohn, accompanying this letter is an additional document describing the Monsanto licensee seed conditioner's qualification for seed mix refuge products. This document, in addition to the submission on January 28, 2011 clarifying Monsanto's manufacturing process and standards, addressing both Monsanto-owned and licensee operated facilities should help clarify Monsanto's Refuge Assurance Program for seed mix refuge products (RIB).

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

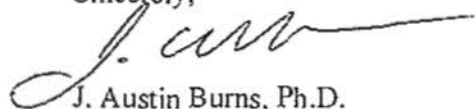
- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	A
Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	A
Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	B

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,



J. Austin Burns, Ph.D.  
Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD  
Dr. Alan Reynolds, EPA BPPD  
Dr. Russell P. Schneider, Monsanto Company

MONSANTO



**TRANSMITTAL DOCUMENT**

**SUBMITTED BY**

Monsanto Company  
800 N. Lindbergh Blvd.  
St. Louis, MO 63167

**REGULATORY ACTION IN SUPPORT OF WHICH  
THIS DOCUMENT IS SUBMITTED**

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's  
Qualification for Seed Mix Refuge Products (RIB)

EPA File Symbol 524-LOL

**TRANSMITTAL DATE**

February 14, 2011

**MONSANTO REFERENCE No.**

07-CR-192E-E2

**LIST OF SUBMITTED DOCUMENTS**

**Administrative Materials**

Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

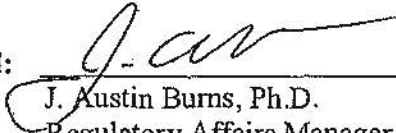
MRID Number \_\_\_\_\_

**EPA Requested Information**

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

MRID Number \_\_\_\_\_

Company Official: \_\_\_\_\_

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
(314) 694-6514

\_\_\_\_\_

2-14-2011

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.  
Senior Director, Regulatory Affairs and Policy  
(202) 383-2866

MONSANTO



**Administrative Materials for Monsanto Protocol/Refuge Assurance Program,  
including Licensee Seed Conditioner's Qualification for  
Seed Mix Refuge Products (RIB)**

(Genuity<sup>®</sup> SmartStax<sup>®</sup>; EPA File Symbol 524-LOL)

United States  
**Environmental Protection Agency**  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier  
Number

**Application for Pesticide – Section I**

1. Company/Product Number EPA File Symbol 524-LOL	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	PM # 92	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section – II**

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

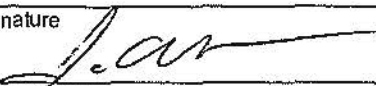
**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

**Section – III**

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section – IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Dr. Russell P. Schneider	Title Sr. Director for Regulatory Affairs & Policy	Telephone No. (Include Area Code) (202) 383-2866
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  <b>(Stamped)</b>
2. Signature 	3. Title Regulatory Affairs Manager	
4. Typed Name J. Austin Burns Ph.D. Tel. (314) 694-6514	5. Date February 14, 2011	

Please read instructions on reverse before completing form.

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95



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## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514  
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167EPA Registration Number / File Symbol:  
524-LOLActive Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* CryIA.105,  
Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-  
ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in  
MON 89034 x TC1507 x MON 88017 x DAS-59122-7Date:  
February 14, 2011General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158:  
Terrestrial field cropProduct Name: MON 89034 x TC1507 x  
MON 88017 x DAS-59122-7

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

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☐ (Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)  
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

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I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

2-14-2011

Typed or Printed Name and Title

J. Austin Burns  
Regulatory Affairs Manager



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## DATA MATRIX

Date: February 14, 2011

EPA Reg. No./File Symbol: 524-LOL Page 1 of 1

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 × TC1507 × MON 88017  
× DAS-59122-7

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Company	OWN	This Application
	Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs ManagerDate  
February 14, 2011

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401 M Street, S.W.  
Washington, D.C. 20460

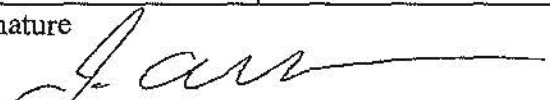
Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: February 14, 2011	EPA Reg. No./File Symbol: 524-LOL	Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Additional Supporting Manufacturing Information
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date February 14, 2011	

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Public File Copy

**Pages 358 - 365**

**\*Access to FIFRA health and safety data is restricted under FIFRA section 10(g)\***

2-14-2011

#### Proposed language on Monsanto seed-mix conditioner certification

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 with interspersed in-field refuge can only be used by growers planting seed corn specifically generated by qualified seed conditioners licensed by the registrant (Monsanto).

Monsanto must implement a Blended Seed Refuge Assurance Program designed to ensure SmartStax seed mix refuge products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
  2. A Quality Management System (QMS) that will include Standard Operating Procedure(s) for the blending process;
  3. Calibration of blending equipment; and
  4. Records and data retention records for seed blend products.
- Calibration records – Monsanto and/or licensees will retain equipment calibration documentation for a specified period of time including the procedure, date of calibration, and the results.
  - Blend proportion records (weight and kernel based) – Monsanto and/or licensees will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight, and the actual weights of the seeds that are blended together to make up the SmartStax seed mix refuge product by seed lot.

Facilities that condition RIB products will be responsible for meeting the product and process requirements provided by Monsanto. Such licensed facilities/conditioner must be qualified by Monsanto prior to producing the 95/5% MON 89034 × TC1507 × MON 88017 × DAS-59122-7/non-Bt corn seed mixture for commercial sale (RIB). In order to qualify, Monsanto will require all facilities, including licensees to implement and maintain a Quality Management System (QMS). Key elements of these processes are to be captured as a licensee qualification Refuge Assurance Program. Under this qualification program, a product facility/conditioner will be required to certify that RIB products it produces under this program meet or exceed the Monsanto-mandated product requirements, including a minimum of 5% non-Bt refuge seed per seed lot. Monsanto will validate the facilities/conditioner (site) qualification through appropriate auditing of the QMS and processes relevant to the Monsanto-mandated product requirements. Conditioners will be audited annually. These facilities must document and retain the required information necessary to demonstrate compliance with product and process requirements, and retain documentation of compliance under their QMS program, and as provided by Monsanto under the process requirements. Records of validation inspections for facilities/conditioner compliance will be kept by Monsanto for a minimum period of three years on a rotating schedule. Licensed RIB facilities/conditioners will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results. Licensed RIB facilities/conditioners will also retain documentation

for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up a RIB product by seed lot. Licensed RIB facilities/conditioners will maintain paper and/or electronic production records for a period of at least three years after the lot is sold.

## PRODUCT LABEL

The subject of this application is for the combined plant-incorporated protectants (PIPs), *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in corn (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 to allow an IRM interspersed in-field refuge configuration. This refuge configuration is enabled by a seed-mixture containing PIP and non-PIP seed. The proposed label for the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, to support an interspersed in-field refuge is attached.

Plant-Incorporated Protectant Label

**MON 89034 × TC1507 × MON 88017 × DAS-59122-7**

**Insect-Protected, Herbicide-Tolerant Corn**

**(Alternate Brand Name Genuity® SmartStax® RIB Complete)†**

**(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 ×**

**MON-88017-3 × DAS-59122-7)**

**Active Ingredients:**

*Bacillus thuringiensis* Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3) ..... ≤ 0.0026%\*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3) ..... ≤ 0.0053%\*

*Bacillus thuringiensis* Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS-01507-1) .. ≤ 0.0012%\*

*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88017-3) ..... ≤ 0.0079%\*

*Bacillus thuringiensis* Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0194%\*

*Bacillus thuringiensis* Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.0042%\*

**Other Ingredients:**

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ..... ≤ 0.0052%\*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ..... ≤ 0.00045%\*

\*Maximum percent (wt/wt) of dry forage

† Genuity® SmartStax® RIB Complete seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

NET CONTENTS \_\_\_\_\_

EPA Registration No. 524-XXX  
EPA Establishment No. 524-MO-002

Monsanto Company  
800 North Lindbergh Blvd.  
St. Louis, MO 63167

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the IRM/Grower Guide for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by an IRM/Grower Guide which includes information on planting, production, and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *Bt* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 must include the refuge size requirement in text and graphical format.

## INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The following information regarding refuge placement for commercial production must be included in the Grower Guide.

This product includes refuge that is interspersed within the field by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed. **The seed mix refuge option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 satisfies the refuge requirements in all regions other than in cotton growing regions where corn earworm is a significant pest as defined below.** The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

### **Additional refuge requirements in cotton-growing regions where corn earworm is a significant pest**

In cotton-growing regions where corn earworm is a significant pest, as defined below, the seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of 95/5 MON 89034 × TC1507 × MON 88017 × DAS-59122-7/non-Bt corn seed mixture planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the 95/5% MON 89034 × TC1507 × MON 88017 × DAS-59122-7/non-Bt corn seed mixture should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the 95/5 MON 89034 × TC1507 × MON 88017 × DAS-59122-7/non-Bt corn seed mixture field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran

damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of SmartStax® (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

#### Corn Insects Controlled or Suppressed

European corn borer (ECB)	<i>Ostrinia nubilalis</i>
Southwestern corn borer (SWCB)	<i>Diatraea grandiosella</i>
Southern cornstalk borer (SCSB)	<i>Diatraea crambidoides</i>
Corn earworm (CEW)	<i>Helicoverpa zea</i>
Fall armyworm (FAW)	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Lesser corn stalk borer	<i>Elasmopalpus lignosellus</i>
Sugarcane borer (SCB)	<i>Diatraea saccharalis</i>
Western bean cutworm (WBC)	<i>Richia albicosta</i>
Black cutworm	<i>Agrotis ipsilon</i>
Western corn rootworm (WCRW)	<i>Diabrotica virgifera virgifera</i>
Northern corn rootworm (NCRW)	<i>Diabrotica barberi</i>
Mexican corn rootworm (MCRW)	<i>Diabrotica virgifera zeae</i>

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: \_\_/\_\_/\_\_

MONSANTO



483696-00

January 28, 2011

Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD.  
ST. LOUIS, MISSOURI 63167  
<http://www.monsanto.com>

Attn: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

Subject: Additional information regarding the manufacturing process for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

Dear Dr. Reilly:

Thank you for the opportunity to review our independent notes resulting from the Scientific Advisory Panel review of the SmartStax seed mix refuge registration application held on December 8-9, 2010 (January 19, 2011 meeting). During our discussion, the EPA BPPD requested that Monsanto (EPA File Symbol 524-LOL) and Dow AgroSciences (EPA File Symbol 68467-RA) independently submit further information clarifying the proposed manufacturing standards for the proposed 5% seed mix refuge product. Accompanying this letter is a document clarifying Monsanto's manufacturing process and standards, addressing both Monsanto-owned and operated facilities, as well as future licensees for the proposed 5% seed mix refuge product.

We trust that the provided information will clarify Monsanto's capabilities and responsibilities with respect to the seed blending manufacturing/process as it pertains to managing ILM compliance with a 5% seed mix refuge as per EPA File Symbol 524-LOL. Additionally, we are providing this information to support a timely EPA registration decision of the product *minimally* within the PRIA decision date of April 12, 2011.

Recent EPA registrations for seed mix refuge corn products (e.g. EPA Reg. Nos. 29964-6 and 29964-10) contained conditions of registration with respect to manufacturing expectations. It is our expectation that similar language should be applicable for other seed mix refuge corn products such as EPA File Symbol 524-LOL, and is appended below (with modification as appropriate). The only proposed change to this language is regarding the use of the ISO-9000 "brand" of Quality Management Systems (QMS), thereby allowing for other equivalent or superior QMS brands and operations to be implemented as appropriate for business operations.

[language from EPA Reg. No. 29964-6, as modified in bold font]

Refuge Assurance Program for **SmartStax Seed Mix Refuge Corn**

Monsanto must implement a Blended Seed Refuge Assurance Program designed to ensure **SmartStax seed mix** refuge products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
2. **A Quality Management System (QMS)**, which will include Standard Operating Procedures for the blending process;
3. Calibration of blending equipment; and
4. Records and data retention records for seed blend products.
  - Calibration records – **Monsanto** and/or licensees will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
  - Blend proportion records (weight and kernel based) – **Monsanto and/or Licensees** will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight, and the actual weights of the seeds that are blended together to make up the **SmartStax seed mix** refuge product by seed lot.

All records must be maintained at the **Monsanto and/or Licensee** blending facility and must be available for the EPA review upon request.

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

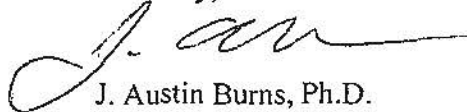
- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	A
Administrative Materials for Additional Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL )	A
Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 x TCI507 x MON 88017 x DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL )	B

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,



J. Austin Burns, Ph.D.

Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD  
Dr. Alan Reynolds, EPA BPPD  
Dr. Russell P. Schneider, Monsanto Company  
Dr. Graham Head, Monsanto Company

MONSANTO



**TRANSMITTAL DOCUMENT**

**SUBMITTED BY**

Monsanto Company  
800 N. Lindbergh Blvd.  
St. Louis, MO 63167

**REGULATORY ACTION IN SUPPORT OF WHICH  
THIS DOCUMENT IS SUBMITTED**

Information regarding the manufacturing process for a 5% seed mix refuge for MON 89034 ×  
TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®)

EPA File Symbol 524-LOL

**TRANSMITTAL DATE**

January 28, 2011

**MONSANTO REFERENCE No.**

07-CR-192E-E2

## LIST OF SUBMITTED DOCUMENTS

### Administrative Materials

Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

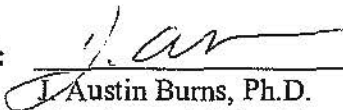
MRID Number \_\_\_\_\_

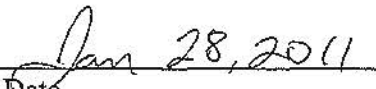
### EPA Requested Information

Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

MRID Number 48389801

Company Official:

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
(314) 694-6514

  
Date Jan 28, 2011

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.  
Senior Director, Regulatory Affairs and Policy  
(202) 383-2866



**MON 89034 × TC1507 × MON 88017 × DAS-59122-7  
(Genuity® SmartStax®; EPA File Symbol 524-LOL)**

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000 1001 1002 1003 1004 1005 1006 1007 1008 1009 1010 1011 1012 1013 1014 1015 1016 1017 1018 1019 1020 1021 1022 1023 1024 1025 1026 1027 1028 1029 1030 1031 1032 1033 1034 1035 1036 1037 1038 1039 104

United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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### Application for Pesticide – Section I

1. Company/Product Number EPA File Symbol 524-LOL  Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	2. EPA Product Manager Sheryl Reilly  PM # 92	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____

### Section – II

<input type="checkbox"/> Amendment – Explain below.  <input type="checkbox"/> Resubmission in response to Agency letter dated _____  <input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other – Explain below.
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**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

### Section – III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per Container _____	If "Yes" Package wgt. _____ No. per Container _____		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container _____		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

### Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Dr. Russell P. Schneider	Title Sr. Director for Regulatory Affairs & Policy	Telephone No. (include Area Code) (202) 383-2866	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped)
2. Signature 		3. Title Regulatory Affairs Manager	
4. Typed Name J. Austin Burns Ph.D. Tel. (314) 694-6514		5. Date January 28, 2011	

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95  
 EPA Form 8570-t (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

401 M Street, S. W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514  
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

EPA Registration Number / File Symbol:  
524-LOL

Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7

Date:  
January 28, 2011

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158:  
Terrestrial field crop

Product Name: MON 89034 x TC1507 x  
MON 88017 x DAS-59122-7

**NDTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**Section I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**Section II: GENERAL OFFER TO PAY**

☐ (Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)  
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**Section III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

Jan 28, 2011

Typed or Printed Name and Title

J. Austin Burns  
Regulatory Affairs Manager



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

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## DATA MATRIX

Date: January 28, 2011

EPA Reg. No./File Symbol: 524-LOL

Page 1 of 1

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x TC1507 x MON 88017  
x DAS-59122-7

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	This Application
	Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs ManagerDate  
January 28, 2011

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Monsanto Company

07-CR-192E-E2

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**DATA MATRIX**

Date: January 28, 2011

EPA Reg. No./File Symbol: 524-LOL Page 1 of 1

Applicant's/Registrant's Name & Address:

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Ingredients: *Bacillus thuringiensis* CryIA.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date  
January 28, 2011

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Monsanto Company

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Page 5 of 5

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**Administrative Materials for Information Regarding the Manufacturing  
Process for a 5% Seed Mix Refuge for  
MON 89034 × TC1507 × MON 88017 × DAS-59122-7  
(Genuity<sup>®</sup> SmartStax<sup>®</sup>; EPA File Symbol 524-LOL)**

United States  
**Environmental Protection Agency**  
 Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier  
 Number

**Application for Pesticide – Section I**

1. Company/Product Number EPA File Symbol 524-LOL	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	PM # 92	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section – II**

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

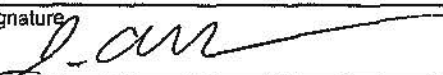
**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

**Section – III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section – IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Dr. Russell P. Schneider	Title Sr. Director for Regulatory Affairs & Policy	Telephone No. (Include Area Code) (202) 383-2866	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped)
2. Signature 		3. Title Regulatory Affairs Manager	
4. Typed Name J. Austin Burns Ph.D. Tel. (314) 694-6514		5. Date January 28, 2011	

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 EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy



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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	EPA Registration Number / File Symbol: 524-LOL
Active Ingredient(s) and/or representative test compound(s): <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2, CrytF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7	Date: January 28, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 x TC1507 x MON 88017 x DAS-59122-7

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**Section I: METHOD OF DATA SUPPORT (Check one method only)**

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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**Section II: GENERAL OFFER TO PAY**

☐ (Required If using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)  
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**Section III: CERTIFICATION**


I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

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I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

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I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date Jan 28, 2011	Typed or Printed Name and Title J. Austin Burns Regulatory Affairs Manager
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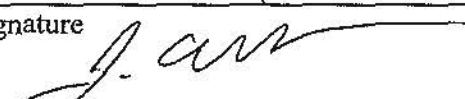
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## DATA MATRIX

Date: January 28, 2011		EPA Reg. No./File Symbol: 524-LOL		Page 1 of 1	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x TC1507 x MON 88017 x DAS-59122-7			
Ingredients: <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	This Application
	Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	Additional Supporting Manufacturing Information
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date January 28, 2011

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DATA MATRIX

Date: January 28, 2011 EPA Reg. No./File Symbol: 524-LOL Page 1 of 1

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x TC1507 x MON 88017  
x DAS-59122-7

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date  
January 28, 2011

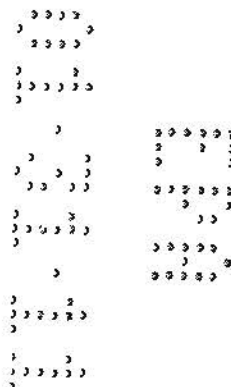
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**Administrative Materials for Information Regarding the Manufacturing  
Process for a 5% Seed Mix Refuge for  
MON 89034 × TC1507 × MON 88017 × DAS-59122-7  
(Genuity<sup>®</sup> SmartStax<sup>®</sup>; EPA File Symbol 524-LOL)**



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier  
Number

**Application for Pesticide – Section I**

1. Company/Product Number EPA File Symbol 524-LOL	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	PM # 92	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section – II**

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

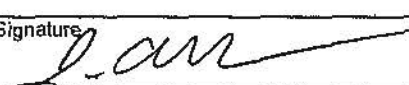
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**Section – III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label Is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section – IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Dr. Russell P. Schneider	Title Sr. Director for Regulatory Affairs & Policy	Telephone No. (Include Area Code) (202) 383-2866	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  <b>(Stamped)</b>
2. Signature 	3. Title Regulatory Affairs Manager		
4. Typed Name J. Austin Burns Ph.D. Tel. (314) 694-6514	5. Date January 28, 2011		

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## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	EPA Registration Number / File Symbol: 524-LOL
Active Ingredient(s) and/or representative test compound(s): <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7	Date: January 28, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 x TC1507 x MON 88017 x DAS-59122-7

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

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## Section I: METHOD OF DATA SUPPORT (Check one method only)

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☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]  
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

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Signature 	Date Jan 28, 2011	Typed or Printed Name and Title J. Austin Burns Regulatory Affairs Manager
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## DATA MATRIX

Date: January 28, 2011

EPA Reg. No./File Symbol: 524-LOL Page 1 of 1

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 × TC1507 × MON 88017  
× DAS-59122-7

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	This Application
	Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date

January 28, 2011

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DATA MATRIX

Date: January 28, 2011	EPA Reg. No./File Symbol: 524-LOL	Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature 	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date January 28, 2011
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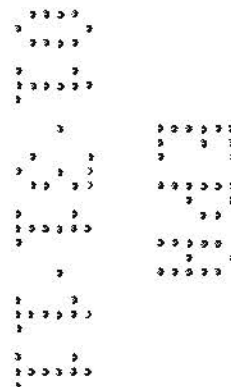
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**Administrative Materials for Information Regarding the Manufacturing  
Process for a 5% Seed Mix Refuge for  
MON 89034 × TC1507 × MON 88017 × DAS-59122-7  
(Genuity® SmartStax®; EPA File Symbol 524-LOL)**



United States <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
<b>Application for Pesticide – Section I</b>			
1. Company/Product Number EPA File Symbol 524-LOL		2. EPA Product Manager Sheryl Reilly	
3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted			
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7		PM # 92	
5. Name and Address of Applicant (include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<b>Section – II</b>			
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other – Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II.) Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)			
<b>Section – III</b>			
1. Material This Product Will Be Packaged in:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. _____ No. per Container _____	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. _____ No. per Container _____	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container _____	
		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
<b>Section – IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Dr. Russell P. Schneider		Title Sr. Director for Regulatory Affairs & Policy	
		Telephone No. (include Area Code) (202) 383-2866	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  <b>(Stamped)</b>
2. Signature 		3. Title Regulatory Affairs Manager	
4. Typed Name J. Austin Burns Ph.D. Tel. (314) 694-6514		5. Date January 28, 2011	

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95  
 EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy



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## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	EPA Registration Number / File Symbol: 524-LOL
Active Ingredient(s) and/or representative test compound(s): <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7	Date: January 28, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 x TC1507 x MON 88017 x DAS-59122-7

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## Section II: GENERAL OFFER TO PAY

☐ [Required If using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]  
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

Jan 28, 2011

Typed or Printed Name and Title

J. Austin Burns  
Regulatory Affairs Manager



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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## DATA MATRIX

Date: January 28, 2011

EPA Reg. No./File Symbol: 524-LOL

Page 1 of 1

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x TC1507 x MON 88017  
x DAS-59122-7

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRIQ Number	Submitter	Status	Note
	Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	This Application
	Volume I: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date

January 28, 2011

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## DATA MATRIX

Date: January 28, 2011

EPA Reg. No./File Symbol: 524-LOL

Page 1 of 1

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x TC1507 x MON 88017  
x DAS-59122-7

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs ManagerDate  
January 28, 2011

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Page 5 of 5

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December 18, 2009

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U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63137  
<http://www.monsanto.com>

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture, EPA Reg. No. 524-XXX.

Dear Dr. Reilly:

Please find the enclosed application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in field corn (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax™) allowing an interspersed in-field refuge option that is enabled by a seed-mixture containing PIP and non-PIP seed. This refuge option is distinct from those allowed under the SmartStax EPA registration No's: 524-581 (Monsanto) and 68467-7 (Dow AgroSciences).

Monsanto Company and Dow AgroSciences (Dow) have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax). This combined trait corn product is comprised of six PIPs encoded by four independent events that have each undergone safety assessments by EPA. Each of these four events, as well as the SmartStax combined trait product has a separate Section 3 registration with the EPA. Permanent tolerance exemptions are in place for each of the six PIP and two inert marker proteins present in the combined trait product, SmartStax. EPA completed the safety and environmental assessment by of SmartStax leading to the Section 3 registrations, 524-581 and 68467-7, in July, 2009. Because SmartStax is currently registered to allow various discrete 5% structured refuge options, additional product descriptors for seed corn specific for the interspersed refuge option would be used to ensure there is no confusion between the two

™ SmartStax is a trademark of Monsanto Technology LLC.

SmartStax product offerings. These additional descriptors would be added prominently to seed corn units and associated labels and literature. Monsanto is committed to ensuring this product clarity, and will present plans for these descriptors to EPA at a later time as they are developed.

Currently, the majority of U.S. corn production utilizing PIP-containing corn requires a 20% non-insect protected (referred to as non-PIP or non-Bt) discrete structured refuge for insect-protected Bt corn. The majority of these products produce a single Bt toxin mode of action (insect control). The strategy to use two or more effective doses with differing modes of action (so-called pyramiding) as an effective way to combat resistance development is supported by academics and regulators as the most effective strategy to foster the durability of insect-protected biotech crops. SmartStax produces three *Bacillus thuringiensis* (Bt) protein toxins each with independent modes of action against lepidopteran corn pests, and two Bt protein toxins with independent modes of insect control against corn rootworms. Each insecticidal mode of action provides an effective dose against these pests. Thus, SmartStax represented a step-change in insect control and insect resistance management (IRM) for corn pests, providing multiple effective modes of action for the control of both above-ground lepidopteran pests and the below-ground corn rootworm (CRW) complex, enabling a significant reduction in the required refuge area (5%) in the U.S. Corn Belt compared with single toxin products (20%).

The IRM conditions of registration for SmartStax under registrations 524-581 and 68467-7 require growers in the U.S. Corn Belt (non-cotton growing areas) to plant 5% of their corn acres with a non-Bt common insect refuge for every 95% of their acres of SmartStax. The non-Bt 'common' refuge supports the production of non-resistant adult insects for both the lepidopteran and corn rootworm pests to mate with the respective surviving insects emerging from SmartStax plants, and thus serves as a refuge for both lepidopteran and corn rootworm pests. This non-Bt refuge corn can be placed as a discrete area, either as in-field strips, perimeter rows, adjacent block, or as a separate block within 1/2 mile from the SmartStax field. The specific refuge requirements are defined according to the prevailing pests in a given region, and whether plantings occur in major cotton growing regions.

Extensive laboratory and field studies, and conservative mathematical modeling, showed that even with the 5% structured refuge, the rate of resistance evolution should be at least three times slower for SmartStax than existing single toxin products utilized with a 20% refuge. Given the significant improvements in insect control efficacy and spectrum, reduction in refuge, overall improvements in yields and potential for elimination of soil-applied pesticides, SmartStax corn has the potential to produce sizable pecuniary and non-pecuniary benefits for farmers and the environment. The multiple effective dose strategy is a central component of the durable IRM refuge strategy for SmartStax, using a 5% refuge in any field configuration.

Although the SmartStax registration provided data and modeling information to support deployment of various 5% discrete structured refuge option in the Corn Belt, Monsanto and Dow have investigated alternative refuge designs over many years. This includes an interspersed refuge approach (commonly referred to as a 'seed mix', or 'refuge in a bag'),

in which a fixed amount of non-Bt seed would be included within each bag of SmartStax seed corn to create a interspersed distribution of non-Bt refuge plants among the SmartStax corn plants across a field. Seed mixes of Bt and non-Bt seed have been recognized as a possible insect resistance management (IRM) strategy for Bt crops for almost two decades because of the value of having an IRM strategy implemented by the technology provider rather than growers. This removes the issue of grower compliance with the IRM strategy and ensures that a refuge will be present within every Bt crop field. Benefits of an interspersed refuge via seed mixes from an IRM perspective include:

- Consistent percentage of non-Bt plants in every Bt field
- An interspersed in-field distribution of non-Bt plants will be particularly beneficial for very large fields
- Reduced probability of mating between Bt-resistant adults
- Appropriate choice of refuge hybrid ensured
- Identical management of Bt and refuge plants
- No additional insecticide use on refuge plants
- Higher adoption of pyramided varieties, increasing the durability of all Bt traits

A major hindrance to enabling the development and deployment of an interspersed refuge structure in the past has been the minimum 20% refuge size necessary to ensure durability (time to resistance development) of single dose products. In-field refuges above 5% caused unacceptable total field yield losses in an interspersed in-field refuge structure. With the development of SmartStax corn containing two- and three- effective insecticide modes of action against targeted pests, the substantial increase in durability supported a reduction in the refuge from 20% to 5%. The durability of SmartStax with a 5% refuge for both above-ground and below-ground pests also strongly supports a 5% interspersed in-field refuge structure, as delivered by planting a seed mix refuge.

The central need for an interspersed refuge – as with any refuge strategy, is that it supports sufficient populations of susceptible target insects while enabling mixing of these insects with any resistant insects surviving in Bt corn fields. Compared with a block refuge, the novel characteristic of a seed mix is the interspersed nature of Bt and non-Bt plants within a field. This spatial distribution will enhance the mixing of adult insects coming from Bt and non-Bt plants, ensuring that any resistant insects surviving on Bt plants will encounter susceptible insects coming from non-Bt plants, which will be beneficial for IRM. However, this spatial distribution of plants in a field also could increase the likelihood that larval insects may move between Bt and non-Bt plants because all non-Bt plants will have neighboring Bt plants. Thus, it is important to quantify the impacts of this larval movement on the refuge function within an interspersed refuge from a seed mix.

Specifically, two criteria need to be met to confirm that a 5% seed mix refuge is as effective as current refuge options for SmartStax. First, the seed mix should not lead to a biologically significant increase in sub-lethal exposure of larvae to the Bt toxins that could increase selection for Bt resistance. This could occur either through early instar larvae of the target pests moving from Bt plants to non-Bt plants after sub-lethal exposure, or by

larvae moving from non-Bt to Bt plants as larger, more Bt-tolerant instars. Assessment of this issue requires examining the susceptibility of larvae of different ages to the proteins in SmartStax. Based on extensive data, the expectation is that the enhanced toxicity conferred by the multiple effective modes of action of SmartStax will make it unlikely that larvae will be able to move and survive in this way, particularly for the highly susceptible lepidopteran target pests. Second, the non-Bt plants in the interspersed field seed mix must support sufficient susceptible pest insects to be an adequate refuge. This can be assessed through direct surveys of pest population density on the non-Bt plants, together with appropriate mathematical modeling.

To this aim, this registration application provides data collected over the past three years assessing the efficacy and value of an interspersed 5% in-field refuge option, via a seed mix containing 5% non-Bt refuge seed + 95% SmartStax seed, as an additional refuge strategy for SmartStax corn in the U.S. Corn Belt. Details of these data and analyses are presented in Volume 2 of this submission. The supporting data and information included in this request include (1) data on larval movement and survival in a 5% interspersed in-field refuge for the key lepidopteran (European corn borer (ECB) and southwestern corn borer (SWCB)) and coleopteran target pests (primarily western corn rootworm (WCR) and secondarily northern corn rootworm (NCR)); (2) mathematical modeling to demonstrate the acceptable risk of a interspersed 5% in-field refuge strategy compared to existing refuge strategies; (3) data on the efficacy of a 5% interspersed refuge against the target pests, and the impact of the non-Bt plants in the interspersed refuge on overall yield; (4) criteria are described for ensuring and verifying a consistent seed mix percentage during the manufacturing process; and additionally, (5) information outlining the benefits for growers, the public, and environment that would result from the addition of an interspersed refuge option for SmartStax (Volume 3 of this submission).

Presented in Volume 2, laboratory and field data indicate that a 5% seed mix will provide an effective refuge for SmartStax for ECB, SWCB, and the CRW species. For all of these pests, the non-Bt plants in a 5% seed mix consistently supported large populations of susceptible insects, while the SmartStax plants had few or no survivors. Highly conservative mathematical modeling shows that an interspersed refuge strategy will provide comparable or greater durability than 5% structured refuge in the Corn Belt, depending upon compliance with the structured refuge, and greater durability than single Bt products with a 20% refuge. Furthermore, this approach will provide yields comparable to current structured refuge systems but with greater convenience and reduced insecticide use on the refuge, thereby bringing additional benefits beyond those of SmartStax with 5% discretely structured refuge.

Presented in Volume 3, the benefits to growers, the environment, and to society at large will be realized by the addition of an interspersed 5% in-field refuge option for SmartStax. Under all 5% refuge options (the strip or block refuge strategy supported in SmartStax registrations 524-581 and 68467-7, and the interspersed 5% in-field refuge proposed with this application), SmartStax represents significant value to U.S. farmers. There are unique benefits to a SmartStax 5% interspersed refuge above those provided by discrete strip or block refuges. These include substantial non-pecuniary grower benefits, environmental

benefits, and improved compliance with IRM requirements. Enabling growers to broadly plant SmartStax corn with an interspersed in-field refuge will support:

- Reduction or potential elimination of application of soil-applied insecticides
- Reduce potential for corn rootworm insecticides in ground or surface water
- Reduce farm worker exposure to organophosphate insecticides, accidental insecticide spills, and insecticide carryover effects
- Increase simplicity, flexibility, and time savings associated with planting the refuge
- Guarantee grower compliance with IRM requirements
- Provide incentive to growers to switch to pyramided Bt technology, improving durability of Bt corn technology

This request for a registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax) will allow an in-field refuge structure in which the non-Bt refuge plants are interspersed within the SmartStax field. This type of interspersed in-field refuge is a 'structured refuge', as defined by EPA (Biopesticides Registration Action Document for Bt Plant-Incorporated Protectants, October 15, 2001), and would be implemented by growers planting a defined seed mixture comprised of PIP (SmartStax) seed with a fixed amount of non-Bt (refuge) seed. In addition, this interspersed refuge would only be implemented via planting a seed-mixture manufactured by the technology provider (registrants) and appropriately licensed seed producer affiliates. This non-Bt refuge would be complementary to, but distinct from, the refuge structures currently allowed under SmartStax registrations 524-581 and 68467-7 (in-field strips, rows, or blocks).

Monsanto and Dow are hereby requesting a registration for the plant-incorporated protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) necessary for their production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration. The interspersed refuge would be implemented via a seed mixture in bags of seed corn consisting of 5% non-Bt corn along with 95% SmartStax corn. Seed mixtures to be planted under this option would only be prepared by seed producers licensed by the registrants to ensure consistency and provide adequate refuge in the field.

The documents accompanying this request are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

- Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

A CD-ROM containing the fully releasable ("A") documents in .pdf format is also provided.

It is Monsanto's understanding from communications with the EPA BPPD, that the following fee category and amount is appropriate based on the PRIA II Fee Table, effective October 1, 2008.

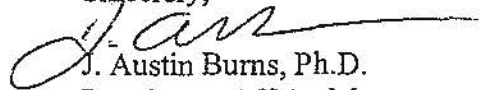
- Fee category: B881. New Product; SAP review required
- Fee category amount: \$82,688

**Documents accompanying this application for registration**

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√	√
N/A	A	Transmittal document	√	√
1	A	Volume 1: Administrative volume (redacted copy)	√	√
1	B	Volume 1: Administrative volume	√	
2	B	Volume 2: Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	√	
3	B	Volume 3: The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn	√	

Should you require any additional information regarding this application please feel free to contact Dr. Russell Schneider at 202-383-2866, or myself at 314-694-6514.

Sincerely,

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD  
Russell Schneider, Ph.D., Monsanto

MONSANTO



**TRANSMITTAL DOCUMENT**

**SUBMITTED BY**

Monsanto Company  
800 N. Lindbergh Blvd.  
St. Louis, MO 63167

**REGULATORY ACTION IN SUPPORT OF WHICH  
THIS DOCUMENT IS SUBMITTED**

Administrative Materials for the Application to Register the Plant-Incorporated  
Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1,  
and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-  
ZMIR39, and PHP17662) Necessary for their Production in  
MON 89034 × TC1507 × MON 88017 × DAS-59122-7,  
With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Registration Number: 524-XXX

**TRANSMITTAL DATE**

December 18, 2009

**MONSANTO REFERENCE No.**

07-CR-192E-2

## LIST OF SUBMITTED DOCUMENTS

### Administrative Materials

**Volume 1.** Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

MRID Number \_\_\_\_\_

### Registration Summary and Data

**Volume 2.** Five Percent Seed Mix Refuge as an Insect Resistance Management Option for

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

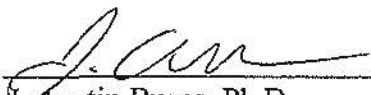
MRID Number 47943701

### Characterization of Benefits

**Volume 3.** The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn

MRID Number 47943702

Company Official:

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
(314) 694-6514

December 18, 2009  
Date

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.  
Senior Director, Regulatory Affairs and Policy  
(202) 383-2866

MONSANTO  
im ine



February 14, 2011

Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63167  
<http://www.monsanto.com>

Attn: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

Subject: Additional information regarding the manufacturing process and refuge assurance program for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

Dear Dr. Reilly:

Thank you and your team for the opportunity to review our proposed manufacturing processes for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on February 3, 2011. As requested by Mike Mendelsohn, accompanying this letter is an additional document describing the Monsanto licensee seed conditioner's qualification for seed mix refuge products. This document, in addition to the submission on January 28, 2011 clarifying Monsanto's manufacturing process and standards, addressing both Monsanto-owned and licensee operated facilities should help clarify Monsanto's Refuge Assurance Program for seed mix refuge products (RIB).

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

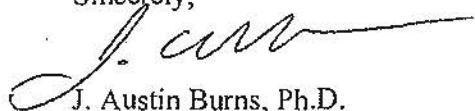
- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	A
Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	A
Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	B

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,



J. Austin Burns, Ph.D.  
Regulatory Affairs Manager, Monsanto Company

cc: Mr. Mike Mendelsohn, EPA BPPD  
Dr. Alan Reynolds, EPA BPPD  
Dr. Russell P. Schneider, Monsanto Company

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**TRANSMITTAL DOCUMENT**

**SUBMITTED BY**

Monsanto Company  
800 N. Lindbergh Blvd.  
St. Louis, MO 63167

**REGULATORY ACTION IN SUPPORT OF WHICH  
THIS DOCUMENT IS SUBMITTED**

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's  
Qualification for Seed Mix Refuge Products (RIB)

EPA File Symbol 524-LOL

**TRANSMITTAL DATE**

February 14, 2011

**MONSANTO REFERENCE No.**

07-CR-192E-E2

**LIST OF SUBMITTED DOCUMENTS**

**Administrative Materials**

Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

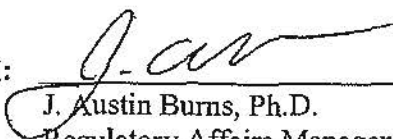
MRID Number \_\_\_\_\_

**EPA Requested Information**

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

MRID Number \_\_\_\_\_

**Company Official:**

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
(314) 694-6514

Date

2-14-2011

**Company Name:** Monsanto Company

**Company Contact:** Russell P. Schneider, Ph.D.  
Senior Director, Regulatory Affairs and Policy  
(202) 383-2866

MONSANTO



**Administrative Materials for Monsanto Protocol/Refuge Assurance Program,  
including Licensee Seed Conditioner's Qualification for  
Seed Mix Refuge Products (RIB)**

(Genuity® SmartStax®; EPA File Symbol 524-LOL)

United States  
**Environmental Protection Agency**  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier  
Number

**Application for Pesticide – Section I**

1. Company/Product Number EPA File Symbol 524-LOL	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7	PM # 92	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section – II**

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

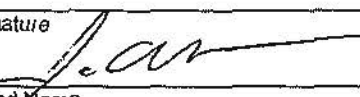
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

**Section – III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per Container
If "Yes" Package wgt.		No. per Container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section – IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Dr. Russell P. Schneider	Title Sr. Director for Regulatory Affairs & Policy	Telephone No. (Include Area Code) (202) 383-2866
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
2. Signature 	3. Title Regulatory Affairs Manager	
4. Typed Name J. Austin Burns Ph.D. Tel. (314) 694-6514	5. Date February 14, 2011	

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95  
EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	EPA Registration Number / File Symbol: 524-LOL
Active Ingredient(s) and/or representative test compound(s): <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7	Date: February 14, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 89034 x TC1507 x MON 88017 x DAS-59122-7

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## Section II: GENERAL OFFER TO PAY

☐ (Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)  
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## Section III: CERTIFICATION


I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date 2-14-2011	Typed or Printed Name and Title J. Austin Burns Regulatory Affairs Manager
--	-------------------	--



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: February 14, 2011

EPA Reg. No./File Symbol: 524-LOL

Page 1 of 1

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x TC1507 x MON 88017  
x DAS-59122-7

Ingredients: *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Company	OWN	This Application
	Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Company	OWN	Additional Supporting Manufacturing Information

Signature

Name and Title

J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date

February 14, 2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

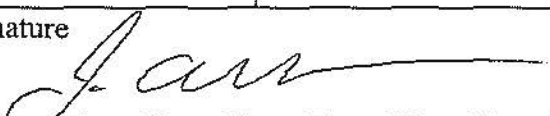
401 M Street, S.W.

Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: February 14, 2011			EPA Reg. No./File Symbol: 524-LOL		Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7		
Ingredients: <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Additional Supporting Manufacturing Information
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date February 14, 2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 12-22-09

Experts In-Processing Signature: B. Rm Date 12-28-09 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>524-LOL</u>		EPA Receipt Date: <u>12-22-09</u>				
Items for Review				Yes	No	N/A
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A) (see comments)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

The inert ingredients CP4 EPSPS + PAT Protc were not clear in OPPEN as to whether it was cleared for use therefore, the page is printed and attached to the CSF. Please confirm whether the inerts are cleared or not. Norman Spurling spoke to a BPPD team member and was told the inerts on the CSF are not in correct format however, we are not clear on that issue. I'm sor that we do not have more answers.

Studies (479437) passed 865 review

MP 12/31/09

479437

\* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRLA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

# CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC)

## REQUEST FORM

CR# 09-322

REQUESTOR NAME: Norman Spaulding		Request date: 12/29/09	
Tel: 305-5835	ORG.: IRMO	CUBE:	MAIL CODE: 7502 P

### CSF ATTACHED:

☒ YES

If CSF is attached complete Item A and the chemical name in item C.

If CSF is not attached complete Item A through C.

from Meigen  
no studies yet

### A. INFORMATION REQUIRED:

☐ Check Applicable Category

☐ Provide PCC and Tolerance Exemption Status For Food-Use Inert ingredient (s).

☐ Provide PCC for Non-Food Use inert Ingredient (s).

☒ Provide PCC for Active Ingredient (s).

☐ Provide PCC for Dye.

☐ Determine if Fragrance is Acceptable for Use In Formulation.

☐ Other (Describe):

### B. PESTICIDE PRODUCT INFORMATION:

MeN 89034 X TE 1507 X MeN 88017 X  
PAS 89122-7

EPA Reg. No/File Symbol: 524-LOL	Product Name:
Registrant: MeN Synto	Food-Use Pesticide: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Percent in Formulation (For Fragrance	/Dyes ) PM 92

### C. INGREDIENT INFORMATION:

Ingredient No.1 should these chems be created individually per the label? See also CSF (page 3 of 11) where indiv components are broken out differently

#### INFORMATION REPORTED:

Chem. Name: Bacillus thuringiensis Cry 1F protein	PCC: 006481
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

#### Ingredient No.2:

Chem. Name: Bacillus thuringiensis Cry 34AB1	PCC: 006496
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

#### Ingredient No.3

Chem. Name: Bacillus thuringiensis Cry 35AB1	PCC: 006490
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

#### Ingredient No.4:

Chem. Name:	PCC:
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Completed By: J. Lock

Date Completed: 12/29/09

12/30/09

Hello Norman

Sheryl Reilly was not in, but I spoke with Alan Reynolds and he advised that these substances should be left in OPPIN as is. He was also able to address the questions on the inerts as well. Thanks for your guidance on this.

Linda Rock



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

December 28, 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-425260  
EPA File Symbol or Registration Number: 524-LOL  
Product Name: MON 89034 X TC1507 X MON 88017 X DAS-59122-7  
EPA Receipt Date: 22-Dec-2009  
EPA Company Number: 524  
Company Name: MONSANTO COMPANY

RUSSELL P. SCHNEIDER  
MONSANTO COMPANY  
MONSANTO COMPANY  
1300 I STREET, NW, SUITE 450 EAST  
WASHINGTON, DC 20005-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B881

NEW PRODUCT;SAP REVIEW REQUIRED;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

A handwritten signature in cursive script, reading "Teresa Downs", is positioned above the typed name.

Front End Processing Staff  
Information Technology & Resources Management Division

**Fee for Service**

16  
{864459S~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_\_

for Division

☐ AD

☒ BPPD

☐ RD

Risk Mgr. 92

Receipt No.

S- 864459

EPA File Symbol/Reg. No.

524-LOL

Pin-Punch Date:

12/22/2009

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B881

Granted: B881

Amount Due: \$ 82,688

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Alan Reynolds Date: 12/23/09

Remarks:

# Receipt for Section 3

S: 854459

Regulation: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 524 MONSANTO COMPANY

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 92

Product #: 524-L0L Product Name: MON 89034 X TC1507 X MON 88017 X DAS-4

Overview#

Me Too Section3: Me Too Product Name:

Application Date: 17-Dec-2009

OPP Rec'd Date: 22-Dec-2009

Front End Date: 23-Dec-2009

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New registration

New Ingredient

Request Date

New Ingredient

Received Date

Form A

Signature Date

Form B

Signature Date

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

# FEE FOR SERVICE

$\rho_{\text{max}} = \frac{\rho_0}{1 - \beta}$

\*Commercial/financial information may be entitled to confidential treatment\*

1801289314

<div style="display: inline-block; vertical-align: middle; text-align: center;">             United States  <b>Environmental Protection Agency</b>              Washington, DC 20460           </div>		<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	<b>OPP Identifier Number</b>  
<b>Application for Pesticide – Section I</b>			
1. Company/Product Number File Symbol 524- <del>XXX</del> 606		2. EPA Product Manager Sheryl Reilly	
Company/Product (Name) MON 89034 × TC1507 × MON 88017 × DAS-59122-7		PM # 92 <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<b>Section – II</b>			
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other – Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II.) Application to Register the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture.			
<b>Section – III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt.      No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt.      No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label Is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
<b>Section – IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Russell P. Schneider, Ph.D.		Title Senior Director, Regulatory Affairs and Policy	
Telephone No. (Include Area Code) (202) 383-2866		6. Date Application Received (Stamped)	
2. Signature 		3. Title Regulatory Affairs Manager	
4. Typed Name J. Austin Burns, Ph.D.      Tel. (314) 694-6514		5. Date December 17, 2009	

MONSANTO  
imagine



December 18, 2009

Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63137  
<http://www.monsanto.com>

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture, EPA Reg. No. 524-XXX.

Dear Dr. Reilly:

Please find the enclosed application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in field corn (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax™) allowing an interspersed in-field refuge option that is enabled by a seed-mixture containing PIP and non-PIP seed. This refuge option is distinct from those allowed under the SmartStax EPA registration No's: 524-581 (Monsanto) and 68467-7 (Dow AgroSciences).

Monsanto Company and Dow AgroSciences (Dow) have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax). This combined trait corn product is comprised of six PIPs encoded by four independent events that have each undergone safety assessments by EPA. Each of these four events, as well as the SmartStax combined trait product has a separate Section 3 registration with the EPA. Permanent tolerance exemptions are in place for each of the six PIP and two inert marker proteins present in the combined trait product, SmartStax. EPA completed the safety and environmental assessment by of SmartStax leading to the Section 3 registrations, 524-581 and 68467-7, in July, 2009. Because SmartStax is currently registered to allow various discrete 5% structured refuge options, additional product descriptors for seed corn specific for the interspersed refuge option would be used to ensure there is no confusion between the two

™ SmartStax is a trademark of Monsanto Technology LLC.

SmartStax product offerings. These additional descriptors would be added prominently to seed corn units and associated labels and literature. Monsanto is committed to ensuring this product clarity, and will present plans for these descriptors to EPA at a later time as they are developed.

Currently, the majority of U.S. corn production utilizing PIP-containing corn requires a 20% non-insect protected (referred to as non-PIP or non-Bt) discrete structured refuge for insect-protected Bt corn. The majority of these products produce a single Bt toxin mode of action (insect control). The strategy to use two or more effective doses with differing modes of action (so-called pyramiding) as an effective way to combat resistance development is supported by academics and regulators as the most effective strategy to foster the durability of insect-protected biotech crops. SmartStax produces three *Bacillus thuringiensis* (Bt) protein toxins each with independent modes of action against lepidopteran corn pests, and two Bt protein toxins with independent modes of insect control against corn rootworms. Each insecticidal mode of action provides an effective dose against these pests. Thus, SmartStax represented a step-change in insect control and insect resistance management (IRM) for corn pests, providing multiple effective modes of action for the control of both above-ground lepidopteran pests and the below-ground corn rootworm (CRW) complex, enabling a significant reduction in the required refuge area (5%) in the U.S. Corn Belt compared with single toxin products (20%).

The IRM conditions of registration for SmartStax under registrations 524-581 and 68467-7 require growers in the U.S. Corn Belt (non-cotton growing areas) to plant 5% of their corn acres with a non-Bt common insect refuge for every 95% of their acres of SmartStax. The non-Bt 'common' refuge supports the production of non-resistant adult insects for both the lepidopteran and corn rootworm pests to mate with the respective surviving insects emerging from SmartStax plants, and thus serves as a refuge for both lepidopteran and corn rootworm pests. This non-Bt refuge corn can be placed as a discrete area, either as in-field strips, perimeter rows, adjacent block, or as a separate block within 1/2 mile from the SmartStax field. The specific refuge requirements are defined according to the prevailing pests in a given region, and whether plantings occur in major cotton growing regions.

Extensive laboratory and field studies, and conservative mathematical modeling, showed that even with the 5% structured refuge, the rate of resistance evolution should be at least three times slower for SmartStax than existing single toxin products utilized with a 20% refuge. Given the significant improvements in insect control efficacy and spectrum, reduction in refuge, overall improvements in yields and potential for elimination of soil-applied pesticides, SmartStax corn has the potential to produce sizable pecuniary and non-pecuniary benefits for farmers and the environment. The multiple effective dose strategy is a central component of the durable IRM refuge strategy for SmartStax, using a 5% refuge in any field configuration.

Although the SmartStax registration provided data and modeling information to support deployment of various 5% discrete structured refuge option in the Corn Belt, Monsanto and Dow have investigated alternative refuge designs over many years. This includes an interspersed refuge approach (commonly referred to as a 'seed mix', or 'refuge in a bag'),

in which a fixed amount of non-Bt seed would be included within each bag of SmartStax seed corn to create a interspersed distribution of non-Bt refuge plants among the SmartStax corn plants across a field. Seed mixes of Bt and non-Bt seed have been recognized as a possible insect resistance management (IRM) strategy for Bt crops for almost two decades because of the value of having an IRM strategy implemented by the technology provider rather than growers. This removes the issue of grower compliance with the IRM strategy and ensures that a refuge will be present within every Bt crop field. Benefits of an interspersed refuge via seed mixes from an IRM perspective include:

- Consistent percentage of non-Bt plants in every Bt field
- An interspersed in-field distribution of non-Bt plants will be particularly beneficial for very large fields
- Reduced probability of mating between Bt-resistant adults
- Appropriate choice of refuge hybrid ensured
- Identical management of Bt and refuge plants
- No additional insecticide use on refuge plants
- Higher adoption of pyramided varieties, increasing the durability of all Bt traits

A major hindrance to enabling the development and deployment of an interspersed refuge structure in the past has been the minimum 20% refuge size necessary to ensure durability (time to resistance development) of single dose products. In-field refuges above 5% caused unacceptable total field yield losses in an interspersed in-field refuge structure. With the development of SmartStax corn containing two- and three- effective insecticide modes of action against targeted pests, the substantial increase in durability supported a reduction in the refuge from 20% to 5%. The durability of SmartStax with a 5% refuge for both above-ground and below-ground pests also strongly supports a 5% interspersed in-field refuge structure, as delivered by planting a seed mix refuge.

The central need for an interspersed refuge – as with any refuge strategy, is that it supports sufficient populations of susceptible target insects while enabling mixing of these insects with any resistant insects surviving in Bt corn fields. Compared with a block refuge, the novel characteristic of a seed mix is the interspersed nature of Bt and non-Bt plants within a field. This spatial distribution will enhance the mixing of adult insects coming from Bt and non-Bt plants, ensuring that any resistant insects surviving on Bt plants will encounter susceptible insects coming from non-Bt plants, which will be beneficial for IRM. However, this spatial distribution of plants in a field also could increase the likelihood that larval insects may move between Bt and non-Bt plants because all non-Bt plants will have neighboring Bt plants. Thus, it is important to quantify the impacts of this larval movement on the refuge function within an interspersed refuge from a seed mix.

Specifically, two criteria need to be met to confirm that a 5% seed mix refuge is as effective as current refuge options for SmartStax. First, the seed mix should not lead to a biologically significant increase in sub-lethal exposure of larvae to the Bt toxins that could increase selection for Bt resistance. This could occur either through early instar larvae of the target pests moving from Bt plants to non-Bt plants after sub-lethal exposure, or by

) )

larvae moving from non-Bt to Bt plants as larger, more Bt-tolerant instars. Assessment of this issue requires examining the susceptibility of larvae of different ages to the proteins in SmartStax. Based on extensive data, the expectation is that the enhanced toxicity conferred by the multiple effective modes of action of SmartStax will make it unlikely that larvae will be able to move and survive in this way, particularly for the highly susceptible lepidopteran target pests. Second, the non-Bt plants in the interspersed field seed mix must support sufficient susceptible pest insects to be an adequate refuge. This can be assessed through direct surveys of pest population density on the non-Bt plants, together with appropriate mathematical modeling.

To this aim, this registration application provides data collected over the past three years assessing the efficacy and value of an interspersed 5% in-field refuge option, via a seed mix containing 5% non-Bt refuge seed + 95% SmartStax seed, as an additional refuge strategy for SmartStax corn in the U.S. Corn Belt. Details of these data and analyses are presented in Volume 2 of this submission. The supporting data and information included in this request include (1) data on larval movement and survival in a 5% interspersed in-field refuge for the key lepidopteran (European corn borer (ECB) and southwestern corn borer (SWCB)) and coleopteran target pests (primarily western corn rootworm (WCR) and secondarily northern corn rootworm (NCR)); (2) mathematical modeling to demonstrate the acceptable risk of a interspersed 5% in-field refuge strategy compared to existing refuge strategies; (3) data on the efficacy of a 5% interspersed refuge against the target pests, and the impact of the non-Bt plants in the interspersed refuge on overall yield; (4) criteria are described for ensuring and verifying a consistent seed mix percentage during the manufacturing process; and additionally, (5) information outlining the benefits for growers, the public, and environment that would result from the addition of an interspersed refuge option for SmartStax (Volume 3 of this submission).

Presented in Volume 2, laboratory and field data indicate that a 5% seed mix will provide an effective refuge for SmartStax for ECB, SWCB, and the CRW species. For all of these pests, the non-Bt plants in a 5% seed mix consistently supported large populations of susceptible insects, while the SmartStax plants had few or no survivors. Highly conservative mathematical modeling shows that an interspersed refuge strategy will provide comparable or greater durability than 5% structured refuge in the Corn Belt, depending upon compliance with the structured refuge, and greater durability than single Bt products with a 20% refuge. Furthermore, this approach will provide yields comparable to current structured refuge systems but with greater convenience and reduced insecticide use on the refuge, thereby bringing additional benefits beyond those of SmartStax with 5% discretely structured refuge.

Presented in Volume 3, the benefits to growers, the environment, and to society at large will be realized by the addition of an interspersed 5% in-field refuge option for SmartStax. Under all 5% refuge options (the strip or block refuge strategy supported in SmartStax registrations 524-581 and 68467-7, and the interspersed 5% in-field refuge proposed with this application), SmartStax represents significant value to U.S. farmers. There are unique benefits to a SmartStax 5% interspersed refuge above those provided by discrete strip or block refuges. These include substantial non-pecuniary grower benefits, environmental

benefits, and improved compliance with IRM requirements. Enabling growers to broadly plant SmartStax corn with an interspersed in-field refuge will support:

- Reduction or potential elimination of application of soil-applied insecticides
- Reduce potential for corn rootworm insecticides in ground or surface water
- Reduce farm worker exposure to organophosphate insecticides, accidental insecticide spills, and insecticide carryover effects
- Increase simplicity, flexibility, and time savings associated with planting the refuge
- Guarantee grower compliance with IRM requirements
- Provide incentive to growers to switch to pyramided Bt technology, improving durability of Bt corn technology

This request for a registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax) will allow an in-field refuge structure in which the non-Bt refuge plants are interspersed within the SmartStax field. This type of interspersed in-field refuge is a 'structured refuge', as defined by EPA (Biopesticides Registration Action Document for Bt Plant-Incorporated Protectants, October 15, 2001), and would be implemented by growers planting a defined seed mixture comprised of PIP (SmartStax) seed with a fixed amount of non-Bt (refuge) seed. In addition, this interspersed refuge would only be implemented via planting a seed-mixture manufactured by the technology provider (registrants) and appropriately licensed seed producer affiliates. This non-Bt refuge would be complementary to, but distinct from, the refuge structures currently allowed under SmartStax registrations 524-581 and 68467-7 (in-field strips, rows, or blocks).

Monsanto and Dow are hereby requesting a registration for the plant-incorporated protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) necessary for their production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration. The interspersed refuge would be implemented via a seed mixture in bags of seed corn consisting of 5% non-Bt corn along with 95% SmartStax corn. Seed mixtures to be planted under this option would only be prepared by seed producers licensed by the registrants to ensure consistency and provide adequate refuge in the field.

The documents accompanying this request are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

- Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

A CD-ROM containing the fully releasable ("A") documents in .pdf format is also provided.

It is Monsanto's understanding from communications with the EPA BPPD, that the following fee category and amount is appropriate based on the PRIA II Fee Table, effective October 1, 2008.

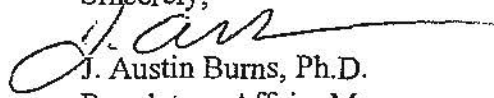
- Fee category: B881. New Product; SAP review required
- Fee category amount: \$82,688

**Documents accompanying this application for registration**

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√	√
N/A	A	Transmittal document	√	√
1	A	Volume 1: Administrative volume (redacted copy)	√	√
1	B	Volume 1: Administrative volume	√	
2	B	Volume 2: Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	√	
3	B	Volume 3: The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn	√	

Should you require any additional information regarding this application please feel free to contact Dr. Russell Schneider at 202-383-2866, or myself at 314-694-6514.

Sincerely,

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD  
Russell Schneider, Ph.D., Monsanto

MONSANTO



**TRANSMITTAL DOCUMENT**

**SUBMITTED BY**

Monsanto Company  
800 N. Lindbergh Blvd.  
St. Louis, MO 63167

**REGULATORY ACTION IN SUPPORT OF WHICH  
THIS DOCUMENT IS SUBMITTED**

Administrative Materials for the Application to Register the Plant-Incorporated  
Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34Ab1,  
and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-  
ZMIR39, and PHP17662) Necessary for their Production in  
MON 89034 × TC1507 × MON 88017 × DAS-59122-7,  
With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Registration Number: 524-XXX

**TRANSMITTAL DATE**

December 18, 2009

**MONSANTO REFERENCE No.**

07-CR-192E-2

## LIST OF SUBMITTED DOCUMENTS

### Administrative Materials

**Volume 1.** Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

MRID Number \_\_\_\_\_

### Registration Summary and Data

**Volume 2.** Five Percent Seed Mix Refuge as an Insect Resistance Management Option for

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

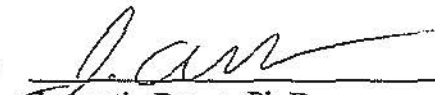
MRID Number \_\_\_\_\_

### Characterization of Benefits

**Volume 3.** The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn

MRID Number \_\_\_\_\_

Company Official:

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
(314) 694-6514

December 18, 2009  
Date

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.  
Senior Director, Regulatory Affairs and Policy  
(202) 383-2866

MONSANTO



**TRANSMITTAL DOCUMENT**

**SUBMITTED BY**

Monsanto Company  
800 N. Lindbergh Blvd.  
St. Louis, MO 63167

**REGULATORY ACTION IN SUPPORT OF WHICH  
THIS DOCUMENT IS SUBMITTED**

Administrative Materials for the Application to Register the Plant-Incorporated  
Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1,  
and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-  
ZMIR39, and PHP17662) Necessary for their Production in  
MON 89034 × TC1507 × MON 88017 × DAS-59122-7,  
With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Registration Number: 524-XXX

**TRANSMITTAL DATE**

December 18, 2009

**MONSANTO REFERENCE No.**

07-CR-192E-2

## LIST OF SUBMITTED DOCUMENTS

### Administrative Materials

**Volume 1.** Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

MRID Number \_\_\_\_\_

### Registration Summary and Data

**Volume 2.** Five Percent Seed Mix Refuge as an Insect Resistance Management Option for

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

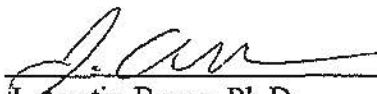
MRID Number \_\_\_\_\_

### Characterization of Benefits

**Volume 3.** The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn

MRID Number \_\_\_\_\_

Company Official:

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
(314) 694-6514

December 18, 2009  
Date

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.  
Senior Director, Regulatory Affairs and Policy  
(202) 383-2866

MONSANTO  
imagine



December 18, 2009

Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

MONSANTO COMPANY  
800 NORTH LINDBERGH BLVD  
ST. LOUIS, MISSOURI 63137  
<http://www.monsanto.com>

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture, EPA Reg. No. 524-XXX.

Dear Dr. Reilly:

Please find the enclosed application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in field corn (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax<sup>TM</sup>) allowing an interspersed in-field refuge option that is enabled by a seed-mixture containing PIP and non-PIP seed. This refuge option is distinct from those allowed under the SmartStax EPA registration No's: 524-581 (Monsanto) and 68467-7 (Dow AgroSciences).

Monsanto Company and Dow AgroSciences (Dow) have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax). This combined trait corn product is comprised of six PIPs encoded by four independent events that have each undergone safety assessments by EPA. Each of these four events, as well as the SmartStax combined trait product has a separate Section 3 registration with the EPA. Permanent tolerance exemptions are in place for each of the six PIP and two inert marker proteins present in the combined trait product, SmartStax. EPA completed the safety and environmental assessment by of SmartStax leading to the Section 3 registrations, 524-581 and 68467-7, in July, 2009. Because SmartStax is currently registered to allow various discrete 5% structured refuge options, additional product descriptors for seed corn specific for the interspersed refuge option would be used to ensure there is no confusion between the two

<sup>TM</sup> SmartStax is a trademark of Monsanto Technology LLC.

SmartStax product offerings. These additional descriptors would be added prominently to seed corn units and associated labels and literature. Monsanto is committed to ensuring this product clarity, and will present plans for these descriptors to EPA at a later time as they are developed.

Currently, the majority of U.S. corn production utilizing PIP-containing corn requires a 20% non-insect protected (referred to as non-PIP or non-Bt) discrete structured refuge for insect-protected Bt corn. The majority of these products produce a single Bt toxin mode of action (insect control). The strategy to use two or more effective doses with differing modes of action (so-called pyramiding) as an effective way to combat resistance development is supported by academics and regulators as the most effective strategy to foster the durability of insect-protected biotech crops. SmartStax produces three *Bacillus thuringiensis* (Bt) protein toxins each with independent modes of action against lepidopteran corn pests, and two Bt protein toxins with independent modes of insect control against corn rootworms. Each insecticidal mode of action provides an effective dose against these pests. Thus, SmartStax represented a step-change in insect control and insect resistance management (IRM) for corn pests, providing multiple effective modes of action for the control of both above-ground lepidopteran pests and the below-ground corn rootworm (CRW) complex, enabling a significant reduction in the required refuge area (5%) in the U.S. Corn Belt compared with single toxin products (20%).

The IRM conditions of registration for SmartStax under registrations 524-581 and 68467-7 require growers in the U.S. Corn Belt (non-cotton growing areas) to plant 5% of their corn acres with a non-Bt common insect refuge for every 95% of their acres of SmartStax. The non-Bt 'common' refuge supports the production of non-resistant adult insects for both the lepidopteran and corn rootworm pests to mate with the respective surviving insects emerging from SmartStax plants, and thus serves as a refuge for both lepidopteran and corn rootworm pests. This non-Bt refuge corn can be placed as a discrete area, either as in-field strips, perimeter rows, adjacent block, or as a separate block within 1/2 mile from the SmartStax field. The specific refuge requirements are defined according to the prevailing pests in a given region, and whether plantings occur in major cotton growing regions.

Extensive laboratory and field studies, and conservative mathematical modeling, showed that even with the 5% structured refuge, the rate of resistance evolution should be at least three times slower for SmartStax than existing single toxin products utilized with a 20% refuge. Given the significant improvements in insect control efficacy and spectrum, reduction in refuge, overall improvements in yields and potential for elimination of soil-applied pesticides, SmartStax corn has the potential to produce sizable pecuniary and non-pecuniary benefits for farmers and the environment. The multiple effective dose strategy is a central component of the durable IRM refuge strategy for SmartStax, using a 5% refuge in any field configuration.

Although the SmartStax registration provided data and modeling information to support deployment of various 5% discrete structured refuge option in the Corn Belt, Monsanto and Dow have investigated alternative refuge designs over many years. This includes an interspersed refuge approach (commonly referred to as a 'seed mix', or 'refuge in a bag'),

in which a fixed amount of non-Bt seed would be included within each bag of SmartStax seed corn to create a interspersed distribution of non-Bt refuge plants among the SmartStax corn plants across a field. Seed mixes of Bt and non-Bt seed have been recognized as a possible insect resistance management (IRM) strategy for Bt crops for almost two decades because of the value of having an IRM strategy implemented by the technology provider rather than growers. This removes the issue of grower compliance with the IRM strategy and ensures that a refuge will be present within every Bt crop field. Benefits of an interspersed refuge via seed mixes from an IRM perspective include:

- Consistent percentage of non-Bt plants in every Bt field
- An interspersed in-field distribution of non-Bt plants will be particularly beneficial for very large fields
- Reduced probability of mating between Bt-resistant adults
- Appropriate choice of refuge hybrid ensured
- Identical management of Bt and refuge plants
- No additional insecticide use on refuge plants
- Higher adoption of pyramided varieties, increasing the durability of all Bt traits

A major hindrance to enabling the development and deployment of an interspersed refuge structure in the past has been the minimum 20% refuge size necessary to ensure durability (time to resistance development) of single dose products. In-field refuges above 5% caused unacceptable total field yield losses in an interspersed in-field refuge structure. With the development of SmartStax corn containing two- and three- effective insecticide modes of action against targeted pests, the substantial increase in durability supported a reduction in the refuge from 20% to 5%. The durability of SmartStax with a 5% refuge for both above-ground and below-ground pests also strongly supports a 5% interspersed in-field refuge structure, as delivered by planting a seed mix refuge.

The central need for an interspersed refuge -- as with any refuge strategy, is that it supports sufficient populations of susceptible target insects while enabling mixing of these insects with any resistant insects surviving in Bt corn fields. Compared with a block refuge, the novel characteristic of a seed mix is the interspersed nature of Bt and non-Bt plants within in a field. This spatial distribution will enhance the mixing of adult insects coming from Bt and non-Bt plants, ensuring that any resistant insects surviving on Bt plants will encounter susceptible insects coming from non-Bt plants, which will be beneficial for IRM. However, this spatial distribution of plants in a field also could increase the likelihood that larval insects may move between Bt and non-Bt plants because all non-Bt plants will have neighboring Bt plants. Thus, it is important to quantify the impacts of this larval movement on the refuge function within an interspersed refuge from a seed mix.

Specifically, two criteria need to be met to confirm that a 5% seed mix refuge is as effective as current refuge options for SmartStax. First, the seed mix should not lead to a biologically significant increase in sub-lethal exposure of larvae to the Bt toxins that could increase selection for Bt resistance. This could occur either through early instar larvae of the target pests moving from Bt plants to non-Bt plants after sub-lethal exposure, or by

larvae moving from non-Bt to Bt plants as larger, more Bt-tolerant instars. Assessment of this issue requires examining the susceptibility of larvae of different ages to the proteins in SmartStax. Based on extensive data, the expectation is that the enhanced toxicity conferred by the multiple effective modes of action of SmartStax will make it unlikely that larvae will be able to move and survive in this way, particularly for the highly susceptible lepidopteran target pests. Second, the non-Bt plants in the interspersed field seed mix must support sufficient susceptible pest insects to be an adequate refuge. This can be assessed through direct surveys of pest population density on the non-Bt plants, together with appropriate mathematical modeling.

To this aim, this registration application provides data collected over the past three years assessing the efficacy and value of an interspersed 5% in-field refuge option, via a seed mix containing 5% non-Bt refuge seed + 95% SmartStax seed, as an additional refuge strategy for SmartStax corn in the U.S. Corn Belt. Details of these data and analyses are presented in Volume 2 of this submission. The supporting data and information included in this request include (1) data on larval movement and survival in a 5% interspersed in-field refuge for the key lepidopteran (European corn borer (ECB) and southwestern corn borer (SWCB)) and coleopteran target pests (primarily western corn rootworm (WCR) and secondarily northern corn rootworm (NCR)); (2) mathematical modeling to demonstrate the acceptable risk of a interspersed 5% in-field refuge strategy compared to existing refuge strategies; (3) data on the efficacy of a 5% interspersed refuge against the target pests, and the impact of the non-Bt plants in the interspersed refuge on overall yield; (4) criteria are described for ensuring and verifying a consistent seed mix percentage during the manufacturing process; and additionally, (5) information outlining the benefits for growers, the public, and environment that would result from the addition of an interspersed refuge option for SmartStax (Volume 3 of this submission).

Presented in Volume 2, laboratory and field data indicate that a 5% seed mix will provide an effective refuge for SmartStax for ECB, SWCB, and the CRW species. For all of these pests, the non-Bt plants in a 5% seed mix consistently supported large populations of susceptible insects, while the SmartStax plants had few or no survivors. Highly conservative mathematical modeling shows that an interspersed refuge strategy will provide comparable or greater durability than 5% structured refuge in the Corn Belt, depending upon compliance with the structured refuge, and greater durability than single Bt products with a 20% refuge. Furthermore, this approach will provide yields comparable to current structured refuge systems but with greater convenience and reduced insecticide use on the refuge, thereby bringing additional benefits beyond those of SmartStax with 5% discretely structured refuge.

Presented in Volume 3, the benefits to growers, the environment, and to society at large will be realized by the addition of an interspersed 5% in-field refuge option for SmartStax. Under all 5% refuge options (the strip or block refuge strategy supported in SmartStax registrations 524-581 and 68467-7, and the interspersed 5% in-field refuge proposed with this application), SmartStax represents significant value to U.S. farmers. There are unique benefits to a SmartStax 5% interspersed refuge above those provided by discrete strip or block refuges. These include substantial non-pecuniary grower benefits, environmental

benefits, and improved compliance with IRM requirements. Enabling growers to broadly plant SmartStax corn with an interspersed in-field refuge will support:

- Reduction or potential elimination of application of soil-applied insecticides
- Reduce potential for corn rootworm insecticides in ground or surface water
- Reduce farm worker exposure to organophosphate insecticides, accidental insecticide spills, and insecticide carryover effects
- Increase simplicity, flexibility, and time savings associated with planting the refuge
- Guarantee grower compliance with IRM requirements
- Provide incentive to growers to switch to pyramided Bt technology, improving durability of Bt corn technology

This request for a registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax) will allow an in-field refuge structure in which the non-Bt refuge plants are interspersed within the SmartStax field. This type of interspersed in-field refuge is a 'structured refuge', as defined by EPA (Biopesticides Registration Action Document for Bt Plant-Incorporated Protectants, October 15, 2001), and would be implemented by growers planting a defined seed mixture comprised of PIP (SmartStax) seed with a fixed amount of non-Bt (refuge) seed. In addition, this interspersed refuge would only be implemented via planting a seed-mixture manufactured by the technology provider (registrants) and appropriately licensed seed producer affiliates. This non-Bt refuge would be complementary to, but distinct from, the refuge structures currently allowed under SmartStax registrations 524-581 and 68467-7 (in-field strips, rows, or blocks).

Monsanto and Dow are hereby requesting a registration for the plant-incorporated protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) necessary for their production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration. The interspersed refuge would be implemented via a seed mixture in bags of seed corn consisting of 5% non-Bt corn along with 95% SmartStax corn. Seed mixtures to be planted under this option would only be prepared by seed producers licensed by the registrants to ensure consistency and provide adequate refuge in the field.

The documents accompanying this request are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

- Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

A CD-ROM containing the fully releasable ("A") documents in .pdf format is also provided.

It is Monsanto's understanding from communications with the EPA BPPD, that the following fee category and amount is appropriate based on the PRIA II Fee Table, effective October 1, 2008.

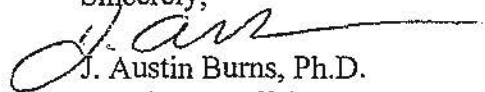
- Fee category: B881. New Product; SAP review required
- Fee category amount: \$82,688

**Documents accompanying this application for registration**

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√	√
N/A	A	Transmittal document	√	√
1	A	Volume 1: Administrative volume (redacted copy)	√	√
1	B	Volume 1: Administrative volume	√	
2	B	Volume 2: Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	√	
3	B	Volume 3: The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn	√	

Should you require any additional information regarding this application please feel free to contact Dr. Russell Schneider at 202-383-2866, or myself at 314-694-6514.

Sincerely,

  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager  
Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD  
Russell Schneider, Ph.D., Monsanto

Dow AgroSciences, LLC  
9330 Zionsville Road  
Indianapolis, IN 46268-1054



December 11, 2009

Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Attn: Dr. Keith Matthews, Esq., Director Biopesticide and Pollution Prevention Division

Subject: Letter authorizing data citation

***Letter of Authorization to Refer to Regulatory Data***

We hereby confirm that Agrigenetics, Inc. d/b/a Mycogen Seeds c/o Dow AgroSciences LLC, on behalf of itself and its affiliates, (collectively, "Dow AgroSciences") authorizes Monsanto Company (Monsanto) to cite, and the U.S. Environmental Protection Agency (EPA) to refer to, data previously submitted by Dow AgroSciences in connection with any of the following products:

- *Insect-protected, glufosinate-tolerant maize containing the Cry1F and PAT proteins, Event TC1507 (DAS-01507-1);*
- *Insect-protected, glufosinate-tolerant maize containing the Cry34/35Ab1 and PAT proteins, Event DAS-59122-7 (DAS-59122-7)*

and all relevant data that Dow AgroSciences has provided EPA to support the Section 3 registration on MON 89034 x TC1507 x MON 88017 x DAS-59122-7, Insect-Protected, Herbicide-Tolerant Corn, EPA registration No. 68467-7, and Dow AgroSciences' pending registration for an interspersed refuge (seed mix) product using MON 89034 x TC1507 x MON 88017 x DAS-59122-7, for the purpose of evaluating and issuing a registration to Monsanto for interspersed refuge (seed mix) product using MON 89034 x TC1507 x MON 88017 x DAS-59122-7.

Dow AgroSciences, LLC  
9330 Zionsville Road  
Indianapolis, IN 46268-1054



December 11, 2009

Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Attn: Dr. Keith Matthews, Esq., Director Biopesticide and Pollution Prevention Division

Subject: Letter authorizing data citation

***Letter of Authorization to Refer to Regulatory Data***

We hereby confirm that Agrigenetics, Inc. d/b/a Mycogen Seeds c/o Dow AgroSciences LLC, on behalf of itself and its affiliates, (collectively, "Dow AgroSciences") authorizes Monsanto Company (Monsanto) to cite, and the U.S. Environmental Protection Agency (EPA) to refer to, data previously submitted by Dow AgroSciences in connection with any of the following products:

- *Insect-protected, glufosinate-tolerant maize containing the CryIF and PAT proteins, Event TC1507 (DAS-01507-1);*
- *Insect-protected, glufosinate-tolerant maize containing the Cry34/35Ab1 and PAT proteins, Event DAS-59122-7 (DAS-59122-7)*

and all relevant data that Dow AgroSciences has provided EPA to support the Section 3 registration on MON 89034 x TC1507 x MON 88017 x DAS-59122-7, Insect-Protected, Herbicide-Tolerant Corn, EPA registration No. 68467-7, and Dow AgroSciences' pending registration for an interspersed refuge (seed mix) product using MON 89034 x TC1507 x MON 88017 x DAS-59122-7, for the purpose of evaluating and issuing a registration to Monsanto for interspersed refuge (seed mix) product using MON 89034 x TC1507 x MON 88017 x DAS-59122-7.

This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any application submitted by any other applicant, for an application by Monsanto for activities other than the registration request as described herein, or for any other regulatory entity to refer to or rely on this data. Dow AgroSciences does not grant permission for citation or reference of this data for any use not specifically stated herein, does not grant permission for citation or reference of data (including future data) not specified herein, and nothing in this agreement grants permission for the U.S. EPA to provide copies of any data to any party.

If you require further information, please contact the undersigned at 317-337-3504.

Best Regards,

A handwritten signature in cursive script, appearing to read "Laura Tagliani".

Laura Tagliani  
Global Regulator Leader – Corn Traits  
Dow AgroSciences LLC

# There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

**CD-ROM with paper application**

then you will find e-label in

**Electronic Label Library**

*If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.*

or

If e-label was submitted via

**XML E-Submission (no paper)**

then you will find e-label in

**Documentum**

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD	Willie Abney	308-1689
	Renae Whitaker	308-7003
	Tracy Lantz	308-6415
BPPD		
RD	Tom Harris	308-9423

# PROCESSING ELECTRONIC LABELS

(rev. 1/5/09, tch)

If e-label submitted via XML e-submission (not on CD-ROM), you may wish to find e-label in Documentum, save e-label to "My Documents", add e-label to ELL, start below at step 5.

## Initial E-Label per application (on CD-ROM with paper via ITRMD)

<sup>1</sup> ITRMD receives paper submission w/ e-label on CD

<sup>2</sup> Tracking record added to OPPIN

<sup>3</sup> ITRMD adds e-label to ELL

<sup>4</sup> ITRMD sends paper submission to AD/BPPD/RD

<sup>5</sup> Connect ELL record with OPPIN S#

in-process

<sup>6</sup> Save copy of e-label from ELL to My Documents

<sup>7</sup> Review label  
(if acceptable, skip to step 20)

<sup>8</sup> Add comments to e-label  
(save; add "with comments" to filename)

<sup>9</sup> Print annotated e-label  
(use "Print with Filename")

review

<sup>10</sup> Send annotated e-label to registrant via email  
(also send "How To Print")

<sup>11</sup> File print of annotated e-label and email in jacket

<sup>12</sup> Add annotated e-label to ELL

<sup>13</sup> Close submission in OPPIN

out-process

## Resubmission (via email to staffer or PM)

<sup>14</sup> Receive email submission w/ e-label attached

<sup>15</sup> Add tracking record to OPPIN

<sup>16</sup> Add e-label to ELL

<sup>17</sup> Connect ELL record with OPPIN S#

in-process

<sup>18</sup> Save copy of e-labels (old & new) from ELL to My Documents

<sup>19</sup> Compare old and new labels with Acrobat

(if revisions needed repeat steps 8-19)

review

<sup>20</sup> Print e-label, stamp, write cover letter  
(use "Print with Filename")

<sup>21</sup> Mail stamped label & cover letter to registrant

<sup>22</sup> File stamped label & cover letter in jacket

<sup>23</sup> Add cover letter to ELL  
(mandatory if accepted with comments)

<sup>24</sup> Close submission in OPPIN

out-process

### process - big picture

- 1- create OPPIN tracking
- 2- put label in ELL; link to S#
- 3- save ELL label to MyDocuments
- 4- compare / comment
- 5- outprocess

### techniques to know

- filename for e-labels
- "print with filename"
- compare / comment
- printing with comments

**Pages 450-455**

**\*Access to FIFRA health and safety data is restricted under FIFRA section 10(g)\***



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167  
(314) 694-6514

EPA Registration Number and File Symbol:

524-XXX

Active Ingredient(s) and/or representative test compound(s):

*Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Date:

December 17, 2009

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158:

Terrestrial field crop

Product Name:

MON 89034 × TC1507 × MON 88017 ×  
DAS-59122-7

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## Section I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).



I am using the selective method of support [or cite-all option under the selective method], and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## Section II: GENERAL OFFER TO PAY



[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

December 17, 2009

Typed or Printed Name and Title

J. Austin Burns  
Regulatory Affairs Manager

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**DATA MATRIX**

Date: December 17, 2009			EPA Reg. No./File Symbol: 524-XXX		Page 1 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 x TC1507 x MON 88017 x DAS-59122-7		
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Role
NA	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture		Monsanto Company	OWN	Administrative This Application
NA	Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 x TC1507 x MON 88017 x DAS-59122-7		Monsanto Company	OWN	Supporting Data This Application
NA	The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn		Monsanto Company	OWN	Benefits This Application
Signature 		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009	

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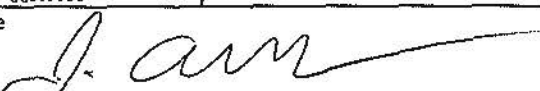
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Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x TC1507 x MON 88017 x  
DAS-59122-7

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34 and Cry35 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7.	474449-00	Monsanto Company	OWN	Administrative
885.1100	Burns, J.A. 2008. Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry3Bb1, Cry1F, Cry34Ab1, and Cry35Ab1 Proteins Produced in MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Monsanto Technical Report MSL0020223.	47444901	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F. 2008. Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Corn Product MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Monsanto Technical Report MSL0021265.	47444902	Monsanto Company	OWN	Product Characterization
885.1100	Taylor, J.P., J.R. Groat, and J.D. Masucci. 2007. Southern Blot Analyses to Confirm the Presence of MON 89034 and MON 88017 in the Combined Trait Corn Product MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Monsanto Technical Report MSL0020682.	47444903	Monsanto Company	OWN	Product Characterization
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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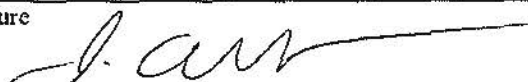
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Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x TC1507 x MON 88017 x  
DAS-59122-7

Ingredient *Bacillus thuringiensis* CryIA.t05, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Schafer, B.W., C. Q. Cia, and S.K. Embrey. 2008. Southern Blot Analyses to Confirm the Presence of TC1507 and DAS-59122-7 in the Combined Trait Corn Product MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Dow AgroSciences Study ID 071179.	47444904	Monsanto Company	OWN	Product Characterization
885.1100	Murphy, J.A. and J.S. McClain. 2008. Summary of CryIA.t05, Cry2Ab2, CryIF, Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Corn Product MON 89034 x TC1507 x MON 88017 x DAS-59122-7 Produced in US Field Trials in 2006. Monsanto Technical Report MSL0021266.	47444905	Monsanto Company	OWN	Product Characterization
885.1100	Stillwell, L. and A. Silvanovich. 2007. Assessment of CryIA.t05, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in the Combined Trait Corn Product MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Monsanto Technical Report MSL0021070.	47444906	Monsanto Company	OWN	Product Characterization
885.1100	Phillips, A.M. 2008. Cry34Ab1, Cry35Ab1, CryIF, and PAT Protein Levels in Hybrid Maize TC1507, DAS-59122-7, MON 89034 x TC1507 x MON 88017 x DAS-59122-7, and a Conventional Control from the Monsanto 2006 Production Plan 06-01-52-04. Dow AgroSciences Study ID 061026.06.	47444907	Monsanto Company	OWN	Product Characterization
N/A	Levine, S. 2008. Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Monsanto Technical Report MSL0021267.	47444908	Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title J. Austin Burris, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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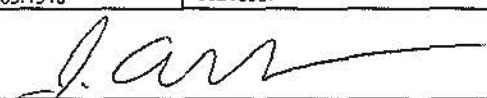
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Date: December 17, 2009		EPA Reg. No./File Symbol: 524-581		Page 4 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x TC1507 x MON 88017 x DAS-59122-7			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	MacRae, T. 2008. Evaluation of Potential for Interaction Between the <i>Bacillus thuringiensis</i> Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins. Monsanto Technical Report MSL0020554	47444909	Monsanto Company	OWN	Environmental Assessment
N/A	Levine, S. 2008. Evaluation of the Potential for Interactions among Cry Proteins Produced by MDN 89034 x TC1507 x MON 88017 x DAS-59122-7 by Insect Bioassay. Monsanto Technical Report MSL0021104.	47444910	Monsanto Company	OWN	Environmental Assessment
N/A	Head, G. and N. Storer. 2008. Insect Resistance Management Plan for MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Monsanto Technical Report MSL0021285.	47444911	Monsanto Company	OWN	IRM
N/A	Levine, S. and J. Huesing. 2008. Endangered Species Impact Assessment for the Combined Trait Corn Product MON 89034 x TC1507 x MON 88017 x DAS-59122-7. Monsanto Technical Report MSL0021268.	47444912	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M. 2008. Evaluation of Potential Dietary Effects of Pollen From the Combined Trait Corn Product MON 89034 x TC1507 x MON 88017 x DAS-59122-7 on the Ladybird Beetle <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL 0021036.	47444913	Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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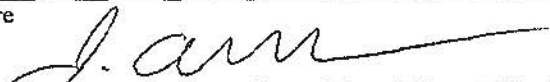


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**DATA MATRIX**

Date: December 17, 2009		EPA Reg. No./File Symbol: 524-575		Page 5 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MDN-89034-3).	469514-00	Monsanto Company	OWN	Administrative
885.1100	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> CryIA.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.	469514-01	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.R. Groat, N.K. Scanlon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	469514-02	Monsanto Company	OWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the CryIA.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Monsanto Company	OWN	Product Characterization
885.1100	Karunanandaa, K., J.J. Thorp, M.E. Golcy, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and <i>E. coli</i> -Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.	469514-04	Monsanto Company	OWN	Product Characterization
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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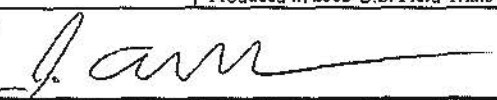


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Date: December 17, 2009		EPA Reg. No./File Symbol: 524-575		Page 6 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in <i>E.Coli</i> and <i>Bt</i> Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	469514-05	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masucci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068	466945-01	Monsanto Company	OWN	Product Characterization
885.1100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the CryIA.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and <i>E.coli</i> -Produced CryIA.105 Proteins. Monsanto Technical Report MSL-19960.	466946-04	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	471275-03	Monsanto Company	OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the CryIA.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Company	OWN	Product Characterization
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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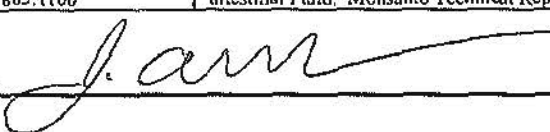


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Date: December 17, 2009			EPA Reg. No./File Symbol: 524-575		Page 7 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034		
Ingredient <i>Bacillus thuringiensis</i> CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the CryIA.105 Protein to CryIA Class of <i>Bacillus thuringiensis</i> Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsanto Company	OWN	Product Characterization
860.1340	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsanto Company	OWN	Product Characterization
885.3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.	469514-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the <i>in vitro</i> Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	469514-07	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S. and E.A. Rice. 2005. Assessment of the <i>in vitro</i> Digestibility of the CryIA.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	469514-08	Monsanto Company	OWN	Human Health Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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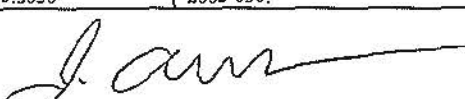
Page 8 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient: *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the CryIA.105 Protein Utilizing the ADS, TOXINS, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Thorp, J.J. and M.E. Goley. 2006. Assessment of the <i>in vitro</i> Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938	469514-09	Monsanto Company	OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the CryIA.105 Protein Utilizing the AD6, TOXINS, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.	469514-10	Monsanto Company	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the <i>in vitro</i> Digestibility of the CryIA.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	466946-06	Monsanto Company	OWN	Human Health Assessment
885.1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and CryIA.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	466946-07	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with CryIA.105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Company	OWN	Human Health Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Monsanto Company

07-CR-192E-2

Page 27 of 175

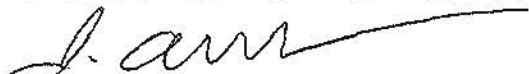


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Date: December 17, 2009		EPA Reg. No./File Symbol: 524-575		Page 9 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient: <i>Bacillus thuringiensis</i> CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXINS, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	469514-11	Monsanto Company	OWN	Human Health Assessment
885.4050	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Control or Commercial Corn. Monsanto Study 05-01-50-13, Amended Report.	469514-12	Monsanto Company	OWN	Human Health Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> CryIA.105 Protein. Monsanto Technical Report MSL-20230.	469514-13	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> Cry2Ab2 Protein. Monsanto Technical Report MSL-20229.	469514-14	Monsanto Company	OWN	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	469514-15	Monsanto Company	OWN	Environmental Assessment
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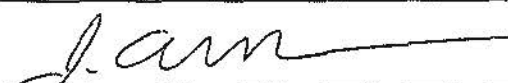
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient: *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola ( <i>Folsomia candida</i> ). Monsanto Technical Report MSL-20169.	469514-16	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran <i>Daphnia magna</i> : An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.	469514-17	Monsanto Company	OWN	Environmental Assessment
885.6200	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to CryIA.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-20147.	469514-18	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a CryIA.105 Protein on Honeybee Larvae ( <i>Apis mellifera</i> L.). Monsanto Study CA-2005-071.	469514-19	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a CryIA.105 Protein on Adult Honeybees ( <i>Apis mellifera</i> L.). Monsanto Study CA-2005-072	469514-20	Monsanto Company	OWN	Environmental Assessment
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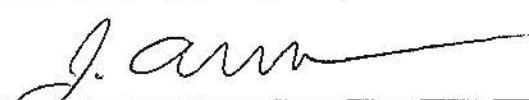
Date: December 17, 2009 EPA Reg. No./File Symbol: 524-575 Page 11 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.	469514-21	Monsanto Company	OWN	Environmental Assessment
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.	469514-22	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthrenidae). Monsanto Technical Report MSL-20170.	469514-23	Monsanto Company	DWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthrenidae). Monsanto Technical Report MSL-20171.	469514-24	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissarius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149.	469514-25	Monsanto Company	OWN	Environmental Assessment
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EPA Reg. No./File Symbol: 524-575

Page 12 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.	469514-27	Monsanto Company	OWN	Environmental Assessment
885.5200	Mueth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and CryIA.105 Proteins. Monsanto Technical Report MSL-20174.	469514-28	Monsanto Company	OWN	Environmental Assessment
N/A	Huesing, J.E., I.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Company	OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the <i>Bacillus Thuringiensis</i> Proteins CryIA.105 and Cry2Ab2. Monsanto Technical Report MSL-19859.	466946-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Poreh, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Monsanto Company	OWN	Environmental Assessment

Signature

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Regulatory Affairs Manager

Date  
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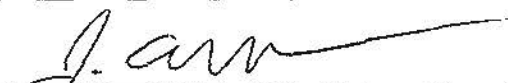


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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.J. and H.O. Krueger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-16177	450863-13	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified <i>Bacillus thuringiensis</i> Cry2Ab2 protein on honey bee larvae. Monsanto Technical Report MSL-16961.	453371-02	Monsanto Company	OWN	Environmental Assessment
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to <i>Collenibola (Folsomia candida)</i> . Amended report. Monsanto Technical Report MSL-16174.	450863-14	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera ( <i>Nasomia vitripennis</i> ). Monsanto Technical Report MSL-16173.	450863-10	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees ( <i>Apis mellifera</i> L.). Monsanto Technical Report MSL-16176.	450863-08	Monsanto Company	OWN	Environmental Assessment
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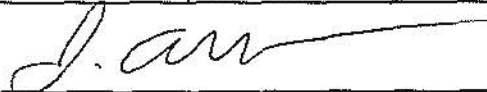
Page 14 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.	469514-30	Monsanto Company	OWN	IRM
	Bogdanova, N. and A. Crawford (2007). Public Interest Document Supporting Registration of <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2 and Cry3Bb1 Proteins in Insect-Protected Corn MON 89034 and MON 89034 x MON 88017	472797-01	Monsanto Company	OWN	Benefits
	Bogdanova, N., S. Dubelman, M. Mueth, J. Murphy and A. Silvanovich (2007). Responses to EPA Questions Regarding Application 524-LTL to register Insect-Protected Corn MON 89034 (MRID 46951428)	471403-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., (2007) Responses to EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	471275-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	470794-02	Monsanto Company	OWN	Misc.
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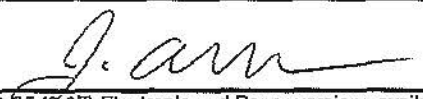
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient B.t. CryIF protein and the genetic material necessary for production (plasmid insert P1HP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Characterization Data for Bacillus thuringiensis var. aizawai CryIF Insect Control Protein as expressed in Maize	447148-01	68467	PER	
	Characterization of Gene Inserts-Bacillus thuringiensis var. aizawai CryIF Insect Control Proteins Expressed in Maize	447148-02	68467	PER	
	Equivalency of Microbial and Maize Expressed CryIF Protein; Characterization of Test Substances for Biochemical and Toxicological Studies. In Vitro Digestibility of Microbial and Maize Expressed	447148-03	68467	PER	
	In Vitro Simulated Intestinal Fluid Digestibility Study of Microbially Derived CryIF (tr)	N/A	68467	PER	
	CryIF B.t. var aizawai Delta-endotoxin: Acute Oral Toxicity Study in Mice	446911-01	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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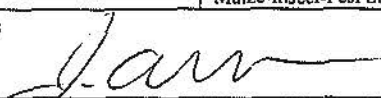


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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t.</i> CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Quantitative ELISA Analysis of CryIF Expression levels in Maize MPS Inbred Lines 1360, 1365, 1366, and 1369. (Interim Report)	44714804	68467	PER	
	Effectiveness Data for <i>Bacillus thuringiensis</i> var. <i>aizawai</i> CryIF Insect Control Protein as Expressed in Maize	44691102	68467	PER	
	Background Document on Resistance Management for <i>Bacillus thuringiensis</i> var. <i>aizawai</i> CryIF Insect Control Protein as Expressed in Maize CryIF Protein Under Simulated Gastric Conditions	44691103	68467	PER	
	Comparison of Amino Acid Sequence Similarity of CryIF and PAT Proteins to Known Allergen Protein	44971701	68467	PER	
	Microbial <i>B.t.</i> CryIF (truncated) Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study	45020101	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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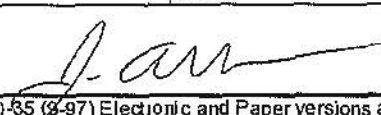
Page 17 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t.* CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-01507-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Characterization of Inserted Genes in Cry IF Maize Line 1507	45020102	68467	PER	
	Characterization of Expressed CryIF Protein in Maize Tissues (Pollen, Grain, Grain-Containing Feed, and Purified Maize-Expressed CryIF Protein) and Microbial Expressed CryIF Delta Endotoxin by Biological and Biochemical Procedures	45020103	68467	PER	
	Quantitative ELISA Analysis of CryIF and PAT Expression levels in and Compositional Analysis of Maize Inbred and Hybrid Lines 1362 and 1507	45020104	68467	PER	
	Phosphinothreine acetyltransferase (PAT) protein: In Vitro Digestibility Study	45041501	68467	PER	
	Non-target Exposure and Risk Assessment for Environmental Dispersal of CryIF Maize Pollen	45041502	68467	PER	
	Environmental Fate of CryIF Protein incorporated into Soil	45020105	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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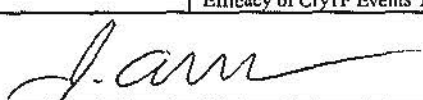


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Date: December 17, 2009		EPA Reg. No./File Symbol: 68467-2		Page 18 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient B.t. CryIF protein and the genetic material necessary for production (plasmid insert PfIP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Chronic Exposure of Folsomia Candida to Bacterially Expressed CryIF Protein	45020107	68467	PER	
	B.t. CryIF Delta-Endotoxin: A 48-Hour Static-Renewal Acute Toxicity Test with the Cladoceran (Daphnia magna) Using Bacterially Expressed B.t. CryIF Delta-Endotoxin, and Pollen from Maize Expressing B.t. CryIF Delta-Endotoxin	45020108	68467	PER	
	Waiver Request: Fish Toxicity Test With Transgenic Maize (Corn) Containing Bacillus thuringiensis var. aizawai (B.t.) CryIF Delta-Endotoxin Delta-Endotoxin	45044201	68467	PER	
	Field Survey of Beneficial Arthropods Associated with Bacillus thuringiensis CryIF Maize	45020113	68467	PER	
	Efficacy of CryIF Events TC1360 and TC1507	45020114	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-2


Page 19 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	CryIF Binding Studies	45020115	68467	PER	
	Evaluation of the Dietary Effect(s) on Honeybee Development Using Bacterially Expressed B.t. CryIF Delta-Endotoxin and Pollen from Maize Expressing B.t. CryIF Delta Endotoxin	45041503	68467	PER	
	CryIF Bacillus Thuringiensis var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	45020106	68467	PER	
	CryIF Bacillus Thuringiensis var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Green Lacewing Larvae	45020109	68467	PER	
	CryIF Bacillus Thuringiensis var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle	45020110	68467	PER	
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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-2

Page 20 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t.* CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	CryIF Bacillus Thuringiensis var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenoptera	45020111	68467	PER	
	Supplement to MRID 44691101: Supplemental Data for Acute Oral Toxicity Study in Mice: CryIF Bacillus thuringiensis var. aizawai delta-endotoxin	45020118	68467	PER	
	Characterization of Inserted Genes in CryIF Maize Line 1507	45010102	68467	PER	
	Resistance Management Plan for Transgenic Maize Expressing the CryIF Insecticidal Protein from Bacillus thuringiensis var. aizawai	45020116	68467	PER	
	Transgenic Corn Expressing Bacillus thuringiensis var. aizawai ( <i>B.t.</i> ) CryIF Delta Endotoxin: A Dietary Toxicity Study with the Northern Bobwhite	45020112	68467	PER	

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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-2

Page 21 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 44714801. Supplemental Data - Product Characterization Data for <i>Bacillus thuringiensis</i> var. <i>aizawai</i> Cry IF Insect Control Protein as Expressed in Maize	45020117	68467	PER	
	High Dose Demonstration For CryIF Events TC1360 and TC 1507: European Corn Borer	45131101	68467	PER	
	Toxicity of the CryIF Protein to Neonate Larvae of the Monarch Butterfly	45131102	68467	PER	
	Public Interest Document for CryIF-Protected Corn (Dow AgroSciences)	45131103	68467	PER	
	Quantitative ELISA Analysis of CryI A(b) Expression Levels in and Composition of Hybrid Lines Derived from Event 176	45131104	68467	PER	

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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-2

Page 22 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t.* CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Thermolability of CryIF (truncated) Delta-Endotoxin	45274801	68467	PER	
	Compositional Analysis of Maize MPS Hybrid Line 1507	45274802	68467	PER	
	CryIF Lateral Flow Test Kit Procedure for Analyzing CryIF Corn Grain	45279301	68467	PER	
	Method Validation Report for the Determination of CryIF Delta-endotoxin Protein in Corn Grain by Enzyme-Linked Immunosorbent Assay	45279302	68467	PER	
	Supplement to MRID 45020109: CryIF Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Green Lacewing Larvae	45307801	68467	PER	

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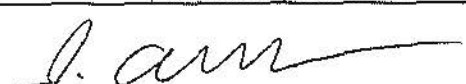


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Date: December 17, 2009		EPA Reg. No./File Symbol: 68467-2		Page 23 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t.</i> Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplement to MRID 45020110: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle	45307802	68467	PER	
	Supplement to MRID 45020111: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenoptera	45307803	68467	PER	
	Supplement to MRID 45020106: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	45307804	68467	PER	
	Supplement to MRID 45041503: Evaluation of the Dietary Effect(s) on Honeybee Development Using Bacterially Expressed Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin	45307805	68467	PER	
	Supplement to MRID #45131102: Supplemental Data-High Dose Demonstration for Cry1F Events TC1360 and TC1507: European Corn Borer	45307701	68467	PER	
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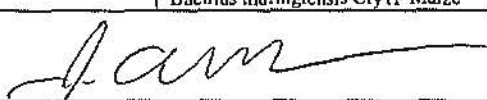
Page 24 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient B.t. CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-01507-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Waiver Request: Fish Toxicity Test to Assess the Potential Effects of Maize Containing <i>Bacillus thuringiensis</i> var. <i>aizawai</i> (Bt) CryIF Insecticidal Crystal Protein (ICP) on Native Fish	45307702	68467	PER	
	Supplement to MRID 45131103: Supplemental Data Public Interest Document for Cry IF-Protected Corn (Dow AgroSciences L.L.C.)	45301101	68467	PER	
	Exposure and risk assessment of Herculex® I Bt field corn pollen to the Karner blue butterfly	45512901	68467	PER	
	Nutritional equivalency of B.t. CryIF maize-poultry feed	45622001	68467	PER	
	Field Survey of Beneficial Arthropods Associated with <i>Bacillus thuringiensis</i> CryIF Maize	45648001	68467	PER	
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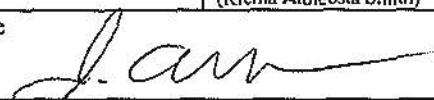


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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Protection			
Ingredient <i>B.t.</i> CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Field Surveys of Non-Target Invertebrate Populations in Bt Corn	45652001	68467	PER	
	Development and Characterization of Enzyme Linked-Immunosorbent Assay (ELISA) for Detection of CryIF Protein	45685601	68467	PER	
	Independent Laboratory Validation of Method GRM 02.13, Determination of CryIF delta-Endotoxin Protein in Corn Grain by an Enzyme Linked Immunosorbent Assay	45685602	68467	PER	
	Supplemental to MRID 45131102: Toxicity of the CryIF Protein to Neonate Larvae of the Monarch Butterfly	45759701	68467	PER	
	Stewardship of Herculex I (PIP) Label with Respect to the Secondary Lepidopteran Pest Western Bean Cutworm ( <i>Richia Albicosta</i> Smith)	45885501	68467	PER	
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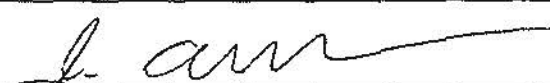
Page 26 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t.* Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Stewardship of Herculex I with respect to the secondary lepidopteran pests lesser cornstalk borer ( <i>Elasmopalpus lignosellus</i> , Zeller), southern corn stalk borer ( <i>Diatraea crambidoides</i> , Grote) and sugarcane borer ( <i>Diatraea saccharalis</i> , Fabricius)	46600201	68467	PER	
	Slide Presentation Summarizing European Corn Borer and Cry1F Resistance Monitoring Update	46695801	68467	PER	
	Research Results on 2004 European Corn Borer Collection from Hamilton County, Iowa	47011201	68467	PER	
	Soil Accumulation of Cry1F Protein after Three Years of Cropping with Herculex	47120701	68467	PER	
	TC1507 Maize and Fall Armyworm in Puerto Rico	47176001	68467	PER	
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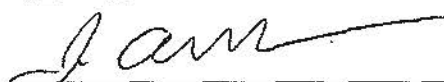
Page 27 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3).

Guideline Reference Number	Guideline Study Name	MRIO Number	Submitter	Status	Note
885.1100	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Produced in MON 88017. MSL-18835	461817-01	Monsanto Company	OWN	Product Characterization
885.1100	Beasley, K. A., H.M. Anderson, P.B. Wimberley, D.W. Mittank, and R.P. Lirette. (2002). Molecular analysis of YieldGard® Rootworm/Roundup Ready® Corn Event MON 88017. MSL-17609	461817-02	Monsanto Company	OWN	Product Characterization
885.1100	Bhakta, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002. MSL-18823	461817-03	Monsanto Company	OWN	Product Characterization
885.1100	Duan, J. J., M. S. Paradise and C. Jiang (2003). Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran species. MSL-18799	461817-04	Monsanto Company	OWN	Product Characterization
885.1100	Hileman, R. E. and J. D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in MON 863. MSL-17137	454240-10	Monsanto Company	OWN	Product Characterization
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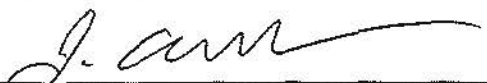


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Date: December 17, 2009		EPA Reg. No./File Symbol: 524-551		Page 28 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 88017			
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E., G. Holleschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by <i>E. coli</i> Fermentation and MON 863. MSL-17274	455382-01	Monsanto Company	OWN	Product Characterization
860.1340	Brown, M. (2003). <i>TraitChek™</i> Cry3Bb Lateral Flow Test Strip and <i>SeedChek™</i> Cry3Bb ELISA Performance Verification for Corn Seed, Leaf, and Composite Testing. MSL-19581, in unpublished study conducted by Strategics Diagnostics, Inc.	463942-01	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y. A., B-P. Tonnu, L. D. Albee and R. P. Lirelle (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. MSL-17181	454240-01	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran Species" (MRID No. 461817-04)	465783-03	Monsanto Company	OWN	Product Characterization
885.1100	Thoma, R. S., G. Holleschak, R. E. Hileman and J. D. Astwood (2001). Primary Structural Protein Characterization of MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154	454240-11	Monsanto Company	OWN	Product Characterization
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Date: December 17, 2009		EPA Reg. No./File Symbol: 524-551		Page 29 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 88017			
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Submission of Supplemental Data (May 21, 2001) in Support of the Application for Registration of MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEL	N/A	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y., B-P. Tonnu and R. P. Lirette (2001). Cry3Bb1, Cry1Ab and NPTII Protein Levels in the Dual-trait Maize Hybrid MON 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. MSL-17266	457917-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of <i>B.t.</i> Protein 11098, <i>B.t.</i> Protein 11231 and NPTII Protein Expressed in Corn Events MON 853 and MON 860 to Microbial Sources. MSL-17222	454240-04	Monsanto Company	OWN	Product Characterization
885.1100	Supplemental Information for "Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002" (MRID No. 461817-03)	465783-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.11098 and NPTII Proteins in Corn Event MDN 863 to Microbial Sources. MSL-17220	454240-05	Monsanto Company	OWN	Product Characterization
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Date: December 17, 2009

EPA Reg. No./File Symbol: 524-551


Page 30 of 57

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Supplemental Information for "Molecular Analysis of YieldGard® Rootworm/Roundup Ready® Corn Event MDN 88017" (MRID No. 461817-02)	465783-01	Monsanto Company	OWN	Product Characterization
860.1340	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. Monsanto Ref. No. 99-640E-1.	453731-01	Monsanto Company	OWN	Product Characterization
N/A	Astwood, J. D., R. E. Hileman, M. J. McKee, T. J. Rydd, J. W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225	454240-09	Monsanto Company	DWN	Human Health Assessment
885.1100	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530	455770-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MDN 853 After Heat Treatment. MSL-17223	454240-07	Monsanto Company	DWN	Human Health Assessment
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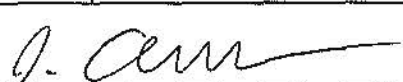
Page 31 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3050	Bechtel, C. L. (1999). Acute Oral Toxicity of <i>B.t.</i> Protein 11231 in Mice. MSL-16216.	449043-05	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140	454240-08	Monsanto Company	OWN	Human Health Assessment
885.3050	Bonnette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Mice with <i>E. coli</i> Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382	455382-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from <i>E. coli</i> . MSL-17292	455382-03	Monsanto Company	OWN	Human Health Assessment
885.3050	Bechtel, C. L. (1999). Acute Oral toxicity of <i>B.t.</i> Protein 11098 in Mice. MSL-16215	449043-06	Monsanto Company	OWN	Human Health Assessment
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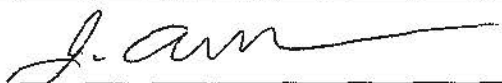


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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 <sup>th</sup> Street, N.W., Suite 660, Washington, D.C. 20005		Product: MON 88017			
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of <i>B.t.</i> Protein t1098 and <i>B.t.</i> Protein t1231 Sequences Utilizing Toxin and Public Domain Genetic Databases. MSL-15870	449043-08	Monsanto Company	OWN	Human Health Assessment
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of <i>B.t.</i> Protein t1098 and <i>B.t.</i> Protein t1231 Sequences Utilizing an Allergen Database. MSL-15873	449043-09	Monsanto Company	OWN	Human Health Assessment
885.1100	Leach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the <i>In Vitro</i> Digestibility of <i>B.t.</i> protein t1098 and <i>B.t.</i> t1231 Utilizing Mammalian Digestive Fate Models. MSL-17166	454240-06	Monsanto Company	OWN	Human Health Assessment
885.4200	McKee, M. J. (2001). Bluegill Dietary Toxicity Study for the <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383	455382-00	Monsanto Company	OWN	Environmental Assessment
885.4240 Series 72, Subdivision E	Drottar, K. R. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein t1098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran ( <i>Daphnia magna</i> ). MSL-16163	449043-18	Monsanto Company	OWN	Environmental Assessment
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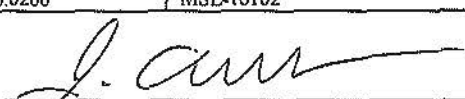
Page 33 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4280	Results of acute toxicity tests with <i>Daphnia</i> and catfish did not produce any evidence of adverse effects. Estuarine and Marine animal studies are waived for this product because of the very low to no potential for exposure to Cry3Bb1 protein from field corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Texiera, D. (2005). Evaluation of Dietary Effects of a Cry3Bb1 Protein Variant on Minute Pirate Bugs ( <i>Orius insidiosus</i> ). MSL-19697	464799-05	Monsanto Company	OWN	Environmental Assessment
885.4300	Since the active ingredient in this product is an insect toxin (Bt endotoxin) that has never shown any toxicity to aquatic or terrestrial plants, these studies have been waived for this product. The Agency has determined there is no significant risk of gene capture and expression of Cry3Bb1 protein by wild or weedy relatives of corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231. Dietary Toxicity Study with the Ladybird Beetle ( <i>Hyppodamia convergens</i> ). MSL-16166	449043-14	Monsanto Company	OWN	Environmental Assessment
850.6200	Hoxter, K. A., S. J. Palmer and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231. An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162	449043-16	Monsanto Company	OWN	Environmental Assessment
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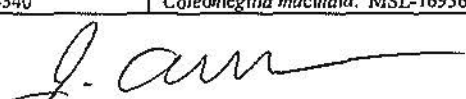
Page 34 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B. t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensis</i> Protein 11098 to Collembola ( <i>Folsomia candida</i> ). MSL-15988	449043-17	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231. A Dietary Study with Green Lacewing Larvae ( <i>Chrysoperla carnea</i> ). MSL-16165	449043-12	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231. A Dietary Study with the Parasitic Hymenoptera ( <i>Nasonia vitripennis</i> ). MSL-16167	449043-13	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., M. Bhatti, B. Ayden, J. Murphy, S. Levine and C. Jiang (2005). Environmental Fate of Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-19285	465103-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16936	453613-01	Monsanto Company	OWN	Environmental Assessment
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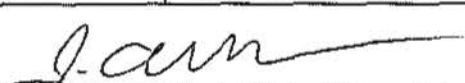
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Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *Bt* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRIQ Number	Submitter	Status	Note
885.4340	Bryan, R. L., J. R. Porsch and H. O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, <i>Hippodamia convergens</i> . MSL-17171	453613-02	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179	455382-06	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., M. J. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16907	455382-04	Monsanto Company	OWN	Environmental Assessment
885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae ( <i>Danix plexippus</i> ) via Laboratory Bioassay. MSL-17235	455382-05	Monsanto Company	OWN	Environmental Assessment
N/A	Head, G., M. Pleau, S. Sivasubramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein <i>in vitro</i> . C3NTO	455382-07	Monsanto Company	OWN	Environmental Assessment
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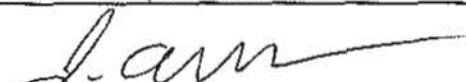
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MON 863. MSL-17614	455770-03	Monsanto Company	OWN	Environmental Assessment
154-2300	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. Monsanto Reference No. 00-CR-032E-7	456530-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Bhatti, M. A., J. D. Duan, C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Report MSL-17531	457916-01	Monsanto Company	OWN	Environmental Assessment
850.6200	Sindermann, A. B., J. R. Porsch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137	457571-01	Monsanto Company	OWN	Environmental Assessment
885.4050	Gallagher, S. P., J. Grimes and J. B. Beavers (1999). <i>Bacillus thuringiensis</i> Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161	449043-15	Monsanto Company	OWN	Environmental Assessment
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Page 37 of 57

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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V. L. (1999). Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees ( <i>Apis mellifera</i> L.). MSL-16169	449043-11	Monsanto Company	OWN	Environmental Assessment
885.5200	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudin (2000). Aerobic Soil Degradation of the <i>B.t.</i> Protein 11098 as a Component of Insect Protected Corn. MSL-16440	451568-04	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected MON 863. MSL-17102	457571-02	Monsanto Company	OWN	Environmental Assessment
885.4050	George, B. (2001). Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. MSL-17243	459415-01	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Honey Bee Larvae. MSL-16168	449043-10	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, J. Colyer, B. Ledesma, S. Levine, F. Lloyd, G. Mueller, J. Warren & C. Jiang (2007) Environmental Fate of the Cry3Bb1 and Cry1Ab Proteins in Corn Fields Planted with MON 863 x MON 810 for Three Consecutive Years MSL-20589	472829-02	Monsanto Company	OWN	Environmental Assessment

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

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Page 38 of 57

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Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-3500	Duan, J., M. Bhatti, C. Brown, G. Head, C. Jiang, C. Pilcher, C. Pilcher, D. Carson & T. Nickson (2007) Two Year Field Assessment of the Effect of Combined Trait Bt Corn Mon 863 x MON 810. MSL-19696	472829-01	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, M.J. McKee, M.A. Nemeth, D. Ward, G. Head, S. Levine, M. Bhatti and M. Paradise (2004). Statistical Power Analysis of a Two-Year Field Study Evaluating the Ecological Effect of Corn Event MON 863. MSL-19246	462627-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Duan J. J., C. Jiang, C. Brown, M. Bhatti, M. Nemeth, T. Nickson and D. Ward (2004). Supplemental Statistical Analysis of Data from a Two-Year Field Census Study with Corn Event MON 863. MSL-19329	463942-02	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman S., M. Bhatti and B. Ayden (2004). Interim Report: Assessment of the Environmental Fate of the Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-18931	462001-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan J. and M. Paradise (2005). Evaluation of Dietary Effects of Cry3Bb1 Protein on the Ground Beetle <i>Poecilus chalcites</i> (Coleoptera:Carabidae). MSL-19631	464799-04	Monsanto Company	OWN	Environmental Assessment
154-3500	Head, G. (2004). Research on the Effects of Corn Rootworm Protected Transgenic Corn on Non-Target Organisms: Publications & Manuscripts.	462627-02	Monsanto Company	OWN	Environmental Assessment

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs ManagerDate  
December 17, 2009

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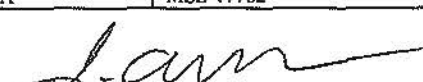
Page 39 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

**Ingredient:** B.t. Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4150	Mammalian wildlife exposure to Cry3Bb1 protein is considered likely; however, the Cry3Bb1 toxicity data for Human Health Assessment indicate that there is no significant toxicity to rodents from testing at the maximum hazard dose. Therefore no hazard to mammalian wildlife is anticipated.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4200	Li, M. H. and E. H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164	449043-19	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003). Data Waiver Request: Toxicity of B.t. Cry3Bb1 Protein in the Red Milkweed Beetle ( <i>Tetraopes</i> sp.). MSL-18741	N/A	Monsanto Company	OWN	Environmental Assessment Granted in BRAD
N/A	Pilcher, C. D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials. Monsanto Ref. No. 00-CR-032E-3	453613-03	Monsanto Company	OWN	Benefits
N/A	Mitchell, P. D. (2002). Yield Benefit of MON 863. MSL-17782	456530-02	Monsanto Company	OWN	Benefits
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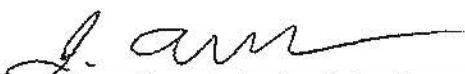
Page 40 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in MON 863. MSL-17766	456530-01	Monsanto Company	OWN	Benefits
N/A	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR12L, ZMIR13L and ZMIR14L). Monsanto Ref. No. 99-781E	450297-01	Monsanto Company	OWN	Benefits
N/A	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - YieldGard® Rootworm. MSL-17993	456923-01	Monsanto Company	OWN	Benefits
N/A	Vaughn, T. T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm ( <i>Diatraea barberti</i> ), Southern Corn Rootworm ( <i>D. undecimpunctata howardi</i> ), and Western Corn Rootworm ( <i>D. virgifera virgifera</i> ). MTC RPT4	455382-08	Monsanto Company	OWN	Benefits
N/A	Vaughn, T., D. Ward, J. Persling, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556	455770-01	Monsanto Company	OWN	Benefits/IRM
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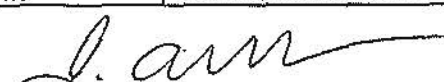
Page 41 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	T. Vaughn (2004). Progress Report on Insect Resistance Management for Corn Event MON 863.	461865-01	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	IRM
N/A	Head, G. and K. Reding. (2006). Corn rootworm Insect Resistance Management Research (fourteen journal publications)	467424-01	Monsanto Company	OWN	IRM
N/A	Davis, P., G. Head, J. McFerson et. al. (2000). Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	451568-05	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4	459438-01	Monsanto Company	OWN	IRM
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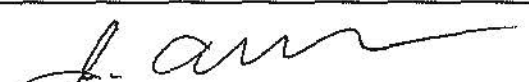


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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				Product: MON 88017	
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	T. Vaughn (2005). Second Progress Report on Insect Resistance Management for Corn Event MON 863. REVISED	N/A	Monsanto Company	OWN	IRM
N/A	Letter submitted May 23, 2003 to EPA with 12 research protocols on the biology and ecology of the corn rootworm pest complex.	N/A	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2004). 2004 Progress Report for the Corn Event MON 863 Resistance Monitoring Program.	462627-01	Monsanto Company	OWN	IRM
N/A	Administrative Materials in Support of the Registration of <i>Bacillus thuringiensis</i> Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	451568-00	Monsanto Company	OWN	Tolerance Exemption
N/A	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant <i>Bacillus thuringiensis</i> Corn Rootworm Control Protein, as Produced in the Corn ( <i>Zea mays</i> , L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	449043-00	Monsanto Company	OWN	Tolerance Exemption
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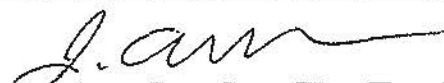
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Petition for Exemption from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients.	PP 7F4888	Monsanto Company	OWN	Tolerance Exemption
885.1100	McCoy, R. L. and A. Sivanovich (2003). Bioinformatics Analysis of the CP4 EPSPS Protein Utilizing the AD4, TOXINS and ALLPEPTIDES Databases. MSL18752	466361-01	Monsanto Company	OWN	Inert Ingredient
885.1100	McCoy, R. L. and A. Sivanovich (2005). Updated Bioinformatics Evaluation of the CP4 EPSPS Protein Utilizing the AD5 Database. MSL19894	466361-02	Monsanto Company	OWN	Inert Ingredient
885.3050	Monsanto Company (1995). Submission of Toxicology Data in Support of a Tolerance Petition for CP4 EPSPS as a Plant Pesticide Formulation Inert Ingredient. Transmittal of 1 Study.	436919-00	Monsanto Company	OWN	Inert Ingredient
885.3050	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgett (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12: 92-419-719	436919-01	Monsanto Company	OWN	Inert Ingredient
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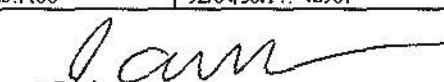


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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017		
Ingredient <i>B.t. Cry3Bb1</i> protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Padgett, S., G. Barry, D. Re, D. Eichholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-Enolpyruvylshikimate-3-phosphate Synthase from <i>Agrobacterium</i> sp. Strain CP4. MSL-12738	438076-01	Monsanto Company	OWN	Inert Ingredient
885.1100	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant <i>Escherichia coli</i> Fermentation. MSL-12389	438076-02	Monsanto Company	DWN	Inert Ingredient
885.1100	Heeren, R., S. Padgett and M. Gustafson (1993). The Purification of Recombinant <i>Escherichia coli</i> CP4 5-enolpyruval-shikimate-3-phosphate synthase for Equivalence Studies. MSL-12574	438076-03	Monsanto Company	OWN	Inert Ingredient
N/A	Monsanto Company (1995). Submission of Product Chemistry, Toxicology and Pesticide Fate in Animals Data in Support of the Exemption for the Requirement of a Petition for Tolerance for CP4 EPSPS. Transmittal of 4 studies.	436433-00	Monsanto Company	DWN	Inert Ingredient
885.1100	Harrison, L., M. Bailey, R. Leimgruber, C. Smith, D. Nida, M. Taylor, M. Gustafson, B. Heeren and S. Padgett (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPS. Lab Project Number: 92/01/30114: 12901	436433-01	Monsanto Company	OWN	Inert Ingredient
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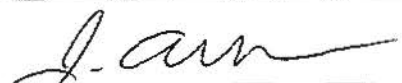
Page 45 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.1.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Lee, T., M. Bailey, C. Smith, J. Zeng, E. Elswick and P. Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in <i>Escherichia coli</i> and European Corn Borer Resistant Corn. Lab Project Number: 94-01-39-10: MSL-13920	436433-02	Monsanto Company	OWN	Inert Ingredient
885.3050	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92223	436433-03	Monsanto Company	OWN	Inert Ingredient
885.1100	Ream, J., M. Bailey, J. Leach and S. Padgett (1993). Assessment of the in vitro Digestive Fate of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949	436433-04	Monsanto Company	OWN	Inert Ingredient
N/A	Revisions and Clarification to the Terms & Conditions of Registration for Corn Event MON 863 and YieldGard® Plus Corn; Progress Report on Multiple IRM-Related Activities for MON 863; and Response to EPA Letter Dated August 13, 2004. Submitted 7/7/2005.	N/A	Monsanto Company	OWN	Terms & Conditions
N/A	Siegfried, B. and T. Spencer (2005). Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 Toxin from <i>Bacillus thuringiensis</i> . This report satisfies the Insect Monitoring Terms & Conditions.	467259-01	Monsanto Company	OWN	Terms & Conditions
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® RW Insect Protection			
Ingredient <i>B.t.</i> Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Phosphinothricin acetyltransferase (PAT) protein: In Vitro Digestibility Study	45041501	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: Acute Toxicity to the Earthworm in an Artificial Substrate	45360201	68467	PER	
	Microbial PS149B1 Binary Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study	45242204	68467	PER	
	Comparison of the Amino Acid Sequence of the <i>Bacillus thuringiensis</i> Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Allergens	45242205	68467	PER	
	PS149B1 14 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242207	68467	PER	
	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242208	68467	PER	
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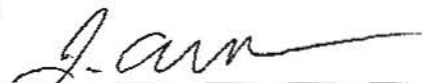
Page 47 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient: B.t. Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 t4 KDa and 44 KDa Proteins: Acute Oral Toxicity study in CD-1 Mice	45242209	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: A Dietary Toxicity Study with the Ladybird Beetle	45242210	68467	PER	
	The Tri-Trophic Interaction Between PS149B1 Transformed Maize, Corn Leaf Aphid and Ladybird Beetle	45242211	68467	PER	
	In Vitro Digestibility of PS149B1 Proteins	45242212	68467	PER	
	Microbial PS149B1 Binary Insecticidal Crystal Protein, Pollen Expressing PS149B1 Binary Insecticidal Crystal Protein, and Individual PS149B1 t4kDa and 44 kDa Insecticidal Crystal Proteins: Evaluation of Dietary Exposure on Honeybee Development	45340701	68467	PER	
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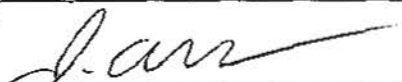
Page 48 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient B.t. Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Thermolability of PS149B1 Binary Delta-Endotoxin	45358401	68467	PER	
	Heat Lability of Individual Proteins of the PS149B1 Binary ICP	45584501	68467	PER	
	In Vitro Simulated Gastric Fluid Digestibility Study of Microbially Derived Cry34Ab1 Protein	45584502	68467	PER	
	Assessment of Chronic Toxicity of Diet Containing Bacillus thuringiensis PS149B1 Insecticidal Crystal Protein to Collembola (Folsomia candida)	45790406	68467	PER	
	Characterization of Cry34Ab1 and Cry35Ab1 from Recombinant Pseudomonas Fluorescence and Transgenic Maize	45790401	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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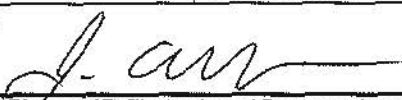


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Date: December 17, 2009		EPA Reg. No./File Symbol: 68467-5		Page 49 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® RW Insect Protection			
Ingredient B.t. Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Walbaum	45790403	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i> Straus	45790404	68467	PER	
	PS149B1 Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera ( <i>Nasonia vitripennis</i> )	45790405	68467	PER	
	PS149B1 Insecticidal Crystal Protein: Dietary Toxicity to Green Lacewing Larvae ( <i>Chrysoperla ruficeps</i> )	45790407	68467	PER	
	SDS-PAGE Sensitivity Analysis for Cry35Ab1 in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212	45790408	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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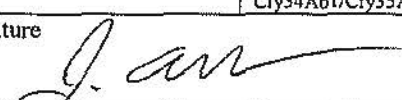
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *Bt* Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Ab1 and Cry35Ab1	45790409	68467	PER	
	Degradation of Microbial Binary PS149B1 Delta-Endotoxin in a Representative Soil from the Mid-Western USA Maize-Growing Region	45242214	68467	PER	
	Characterization of DNA Inserted into Transgenic Corn Events E4497.42.1.34, E4497.45.2.16, E4497.59.1.10, E4497.66.1.27, E4497.71.1.29 and E4497.71.1.33	45790402	68467	PER	
	Field Efficacy of Cry34Ab1/Cry35Ab1 Maize Events Against Corn Rootworms	45790410	68467	PER	
	Summary of Heat Lability Studies with Cry34Ab1/Cry35Ab1	45808601	68467	PER	
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Page 51 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t.* Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP (7662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Slide Presentation Summarizing Cry34Ab1/Cry35Ab1 Heat Inactivation Studies	45860201	68467	PER	
	Independent Laboratory Validation Pioneer Hi-Bred International, Inc. ELISA Method for the Quantification of Cry34Ab1 Protein from Transgenic Plants	46123901	68467	PER	
	Independent Laboratory Validation of Dow AgroSciences Method GRM 03.13, "Determination of Cry35Ab1 Insecticidal Crystal Protein in Maize Tissue by enzyme Linked Immunosorbent Assay"	46123902	68467	PER	
	Cry34/35 Protein Distribution and Familiarity	46123903	68467	PER	
	Agronomic Characteristics, Quantitative ELISA and Nutrient Composition Analysis of Hybrid Maize Lines Containing Cry34Ab1, Cry35Ab1 and PAT Genes: Chile Locations	46123904	68467	PER	

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Regulatory Affairs Manager

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Applicant's/Registrant's Name & Address:

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Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Biological equivalency of Cry34/35Ab1 insecticidal crystal protein in transgenic plants and derived from transgenic <i>Pseudomonas fluorescens</i>	46123905	68467	PER	
	Characterization of Cry34Ab1 and Cry35Ab1 Proteins Derived from Transgenic Maize event E4497.59.1.22 (DAS-59122-7)	46123906	68467	PER	
	Characterization of Phosphinothricin Acetyltransferase (PAT) Derived from Transgenic Maize Event E4497.59.1.22	46123907	68467	PER	
	Characterization of DNA Inserted into Transgenic Corn Events DAS45216-6 and DAS-59122-7	46123908	68467	PER	
	Detailed characterization of DNA inserted into transgenic corn events DAS-45216-6 and DAS-59122-7	46123909	68467	PER	

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Name and Title

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Regulatory Affairs Manager

Date

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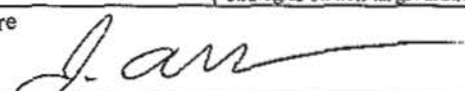
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient B.t. Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Evaluation of microbe derived cry34Ab1 and Cry35Ab1 proteins for protein synthesis inhibition activity	46123910	68467	PER	
	Nutritional Equivalency Study of Maize Containing Cry34Ab1 and Cry35Ab1. Poultry Feeding Study	46123911	68467	PER	
	The effect of Cry34Ab1/Cry35Ab1 proteins on the development and mortality of the Ladybird beetle <i>Colletes maculata</i> DeGeer	46123912	68467	PER	
	Non-target Invertebrate Ecological Risk Assessment for Field Corn Expressing Cry34Ab1 and cry35Ab1 Insecticidal Crystal Proteins in Event DAS-591227	46123913	68467	PER	
	Evaluation of the impact of corn rootworm control strategies on non-target arthropods	46123914	68467	PER	
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Investigations into Dose of Cry34Ab1/Cry35Ab1 Rootworm-Resistant Maize Event DAS-59122-7 Against Western and northern Corn Rootworms in Support of Trait Durability Plans	46123915	68467	PER	
	Effect on Western Corn Rootworm Adults of Feeding on Cry34/35Ab1-Corn Rootworm Protected Corn Tissue and Implications for Product Durability	46123916	68467	PER	
	Evaluation of endangered/threatened insect species relative to the use of Cry34Ab1/Cry35Ab1 corn rootworm-resistant maize hybrids	46123917	68467	PER	
	Trait Durability Plan for Cry34/35-Corn Rootworm Protected corn Event DAS-59122-7 Following Commercialization	46123918	68467	PER	
	Simulations of Corn Rootworm Adaptation to Cry34/35-Corn Rootworm Protected Corn in Support of Trait Durability Plans for Event DAS-59122-7	46123919	68467	PER	

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Regulatory Affairs Manager

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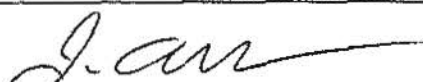
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Digestion of Allergenic and Non-Allergenic Proteins in Simulated Gastric Fluid	46123920	68467	PER	
	Public Interest Document for Cry34/35Ab1 Corn Rootworm-Protected Corn	46123921	68467	PER	
	Evaluation of the Sequence Similarities of the Cry34Ab1, cry35Ab1, and PAT Proteins to the Public Protein Sequence Datasets	46584701	68467	PER	
	OECD. 19. Consensus document of general information concerning the genes and their enzymes that confer tolerance to phosphinothricin herbicide. ENV/JM/MONO(99)13. 26p.		68467	PL	
	Safety evaluation of the phosphinothricin acetyltransferase proteins encoded by the pat and bar sequences that confer tolerance to glufosinate-ammonium herbicide in transgenic plants. Regulatory Toxicology & Pharmacology 41 (2005) 134-149.		68467	PL	
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect Protection		
Ingredient <i>B.t.</i> Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Characterization Data for <i>Bacillus thuringiensis</i> Cry34Ab1 and Cry35Ab1 Proteins Expressed in Transgenic Maize Plants (PHP17662)	45790601	68467	PER	
	Quantitative ELISA Analysis of Cry34Ab1 and Cry35Ab1 Proteins Expressed in Maize Plants Transformed with the Vector PHP17662	45833201	68467	PER	
	Addendum to MRID # 45790601. Product Characterization Data for <i>Bacillus thuringiensis</i> Cry34Ab1 and Cry35Ab1 Proteins Expressed in Transgenic Maize Plants (PHP17662)	46030001	68467	PER	
	Probe MOA Studies to Assess Potential for Protein Synthesis Inhibition by <i>Bacillus thuringiensis</i> PS149B1 cry34Ab1/cry35Ab1 Proteins in a Rabbit Reticulocyte Assay: Re-examination of Lab Notebook Data	45942801	68467	PER	
	Digestion efficiency of allergens and non-allergens in simulated gastric fluid	46388601	68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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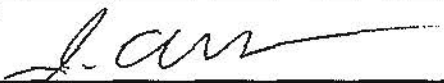
Page 57 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t.* Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Evaluation of the Sequence Similarities of the Cry34Ab1, Cry35Ab1, and PAT Proteins to the Public Protein Sequence Datasets	46584701	68467	PER	
	Investigation of Potential Interaction between CryIF and the Binary Cry34Ab1/Cry35Ab1 Proteins	46343806	68467	PER	
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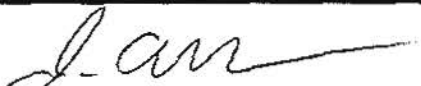
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Date: December 17, 2009	EPA Reg. No./File Symbol: 524-581	Page 1 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 x TC1507 x MON 88017 x DAS-59122-7
Ingredient <i>Bacillus thuringiensis</i> Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507 x MON- 88017-3 x DAS-59122-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Administrative This Application
			Monsanto Company	OWN	Supporting data This Application
			Monsanto Company	OWN	Benefits This Application
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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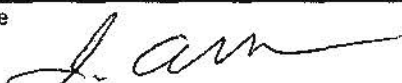


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Date: December 17, 2009			EPA Reg. No./File Symbol: 524-XXX		Page 2 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 x TC1507 x MON 88017 x DAS-59122-7		
Ingredient <i>Bacillus thuringiensis</i> CryIA.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507 x MON-88017-3 x DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Administrative
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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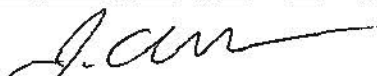
Page 3 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 × TC1507 × MON 88017 ×  
DAS-59122-7

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	DWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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Date: December 17, 2009

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Page 4 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034 x TC1507 x MON 88017 x  
DAS-59122-7

Ingredient *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, CryIF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 x TC1507 x MON 88017 x DAS-59122-7 (OECD Unique Identifier: MON-89034-3 x DAS-01507 x MON-88017-3 x DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Date: December 17, 2009

EPA Reg. No./File Symbol: 524-575

Page 5 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Administrative
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date  
December 17, 2009

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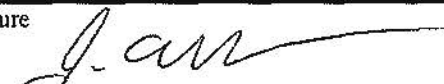


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Date: December 17, 2009		EPA Reg. No./File Symbol: 524-575		Page 6 of 57	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034			
Ingredient <i>Bacillus thuringiensis</i> CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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Date: December 17, 2009

EPA Reg. No./File Symbol: 524-575


Page 7 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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Date: December 17, 2009

EPA Reg. No./File Symbol: 524-575

Page 8 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient: *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	DWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	DWN	Human Health Assessment
			Monsanto Company	DWN	Human Health Assessment

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date  
December 17, 2009

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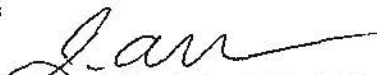
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
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Date: December 17, 2009

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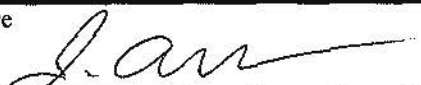
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Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
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Page 11 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
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Page 12 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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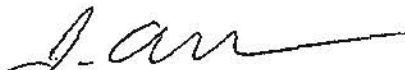
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
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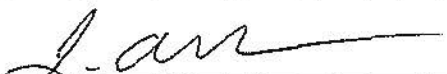
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 89034

Ingredient *Bacillus thuringiensis* CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Misc.
			Monsanto Company	OWN	Misc.
			Monsanto Company	OWN	Misc.
			Monsanto Company	OWN	Misc.
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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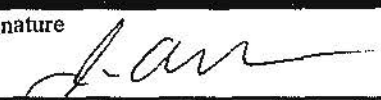


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Date: December 17, 2009			EPA Reg. No./File Symbol: 68467-2		Page 15 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Protection		
Ingredient <i>B.t. Cry1F</i> protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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DATA MATRIX

Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-2


Page 16 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® 1 Insect Protection

Ingredient: B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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**DATA MATRIX**

Date: December 17, 2009			EPA Reg. No./File Symbol: 68467-2		Page 17 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Protection		
Ingredient <i>B.t. CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)</i>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009	

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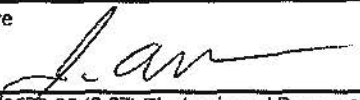


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DATA MATRIX

Date: December 17, 2009			EPA Reg. No./File Symbol: 68467-2		Page 18 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Protection		
Ingredient B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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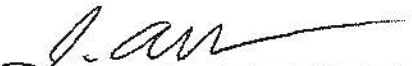
Page 19 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient: *B.t. CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-2


Page 20 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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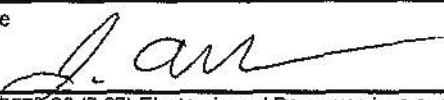


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Date: December 17, 2009			EPA Reg. No./File Symbol: 68467-2		Page 21 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Protection		
Ingredient: B.t. Cry1F protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-2


Page 22 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient B.t. CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-01507-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-2


Page 23 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
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Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Date: December 17, 2009			EPA Reg. No./File Symbol: 68467-2		Page 24 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Protection		
Ingredient <i>B.t. CryIF</i> protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature <i>J. Austin Burns</i>			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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EPA Reg. No./File Symbol: 68467-2


Page 25 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. CryIF* protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-2


Page 26 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® I Insect Protection

Ingredient *B.t. CryIF protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1)*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
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Page 27 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
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EPA Reg. No./File Symbol: 524-551


Page 29 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Page 30 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
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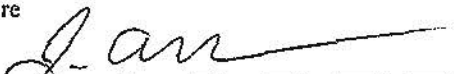
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
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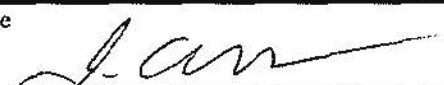
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
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EPA Reg. No./File Symbol: 524-551


Page 33 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment Waived in BRAD
			Monsanto Company	DWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment Waived in BRAD
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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Date: December 17, 2009

EPA Reg. No./File Symbol: 524-551


Page 34 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
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EPA Reg. No./File Symbol: 524-551


Page 35 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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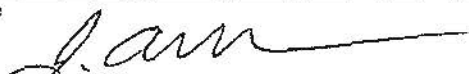
Page 36 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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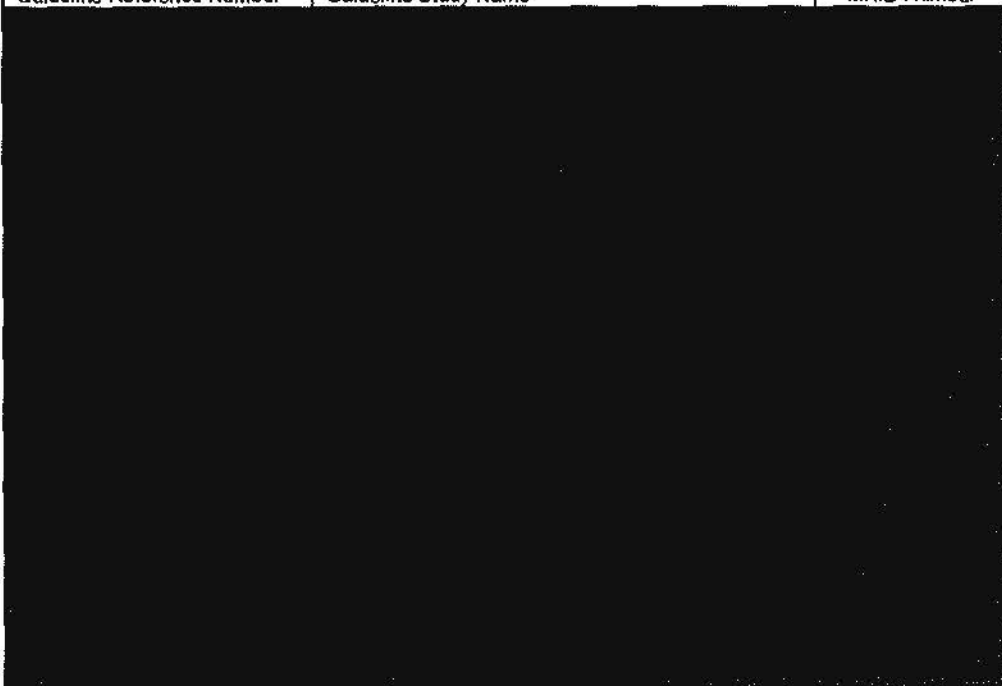
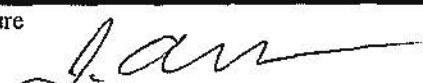
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Date: December 17, 2009			EPA Reg. No./File Symbol: 524-551		Page 37 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017		
Ingredient <i>B.t.</i> Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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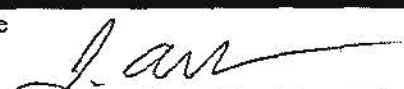
Page 38 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Date: December 17, 2009

EPA Reg. No./File Symbol: 524-551


Page 39 of 57

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	DWN	Environmental Assessment Waived in BRAD
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	DWN	Environmental Assessment Granted in BRAD
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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Date: December 17, 2009

EPA Reg. No./File Symbol: 524-551


Page 40 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits/IRM
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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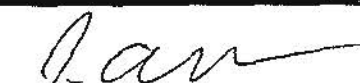
Page 42 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	IRM
			Monsanto Company	OWN	Tolerance Exemption
			Monsanto Company	OWN	Tolerance Exemption
			Signature 		

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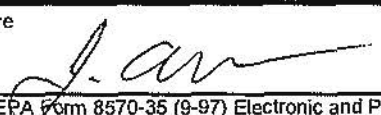


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Date: December 17, 2009			EPA Reg. No./File Symbol: 524-551		Page 43 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017		
Ingredient <i>B.t. Cry3Bb1</i> protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Tolerance Exemption
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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Date: December 17, 2009 EPA Reg. No./File Symbol: 524-551 Page 44 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t. Cry3Bb1* protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Date: December 17, 2009

EPA Reg. No./File Symbol: 524-551


Page 45 of 57

Applicant's/Registrant's Name &amp; Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 88017

Ingredient *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OW	Inert Ingredient
			Monsanto Company	OWN	Terms & Conditions
			Monsanto Company	OWN	Terms & Conditions
			Monsanto Company	OWN	Terms & Conditions
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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-5


Page 46 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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DATA MATRIX

Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-5


Page 47 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

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Date: December 17, 2009			EPA Reg. No./File Symbol: 68467-5		Page 48 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect Protection		
Ingredient <i>B.t.</i> Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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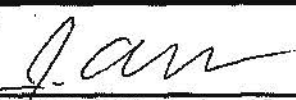


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DATA MATRIX

Date: December 17, 2009			EPA Reg. No./File Symbol: 68467-5		Page 49 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect Protection		
Ingredient <i>B.t. Cry34/35Ab1</i> Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature 			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager		Date December 17, 2009

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Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-5

Page 50 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient B.1. Cry34/35AbI Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date  
December 17, 2009

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DATA MATRIX

Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-5

Page 51 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient: *B.t. Cry34/35Ab I* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	

Signature

Name and Title  
J. Austin Burns, Ph.D.  
Regulatory Affairs Manager

Date  
December 17, 2009

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DATA MATRIX

Date: December 17, 2009

EPA Reg. No./File Symbol: 68467-5

Page 52 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient: *B.t. Cry34/35Abl* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

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DATA MATRIX

Date: December 17, 2009

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Ingredient *Bt Cry34/35Ab1 Insecticidal Crystal protein* and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number

Guideline Study Name

MRID Number

Submitter

Status

Note

Product: Herculex® RW Insect Protection

EPA Reg. No./File Symbol: 68467-5

Page 53 of 57

			68467	PER	
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Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW Insect Protection

Ingredient B.t. Cry34/35Abl Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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EPA Reg. No./File Symbol: 68467-5

Page 55 of 57

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: Herculex® RW *Insect Protection*

Ingredient *B.t. Cry34/35Ab1* Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHPI7662) in corn (OECD Identifier: DAS-59122-7)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PL	
			68467	PL	

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Page 56 of 57

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## SECTION II

### SUMMARY OF THE APPLICATION

Monsanto Company and Dow AgroSciences (Dow) have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax). This combined trait corn product is comprised of six PIPs encoded by four independent events that have each undergone safety assessments by EPA. Each of these four events as well as the SmartStax combined trait product has a separate Section 3 registration with the EPA. Permanent tolerance exemptions are in place for each of the six PIP and two inert marker proteins present in the combined trait product, SmartStax. EPA completed the safety and environmental assessment by of SmartStax leading to the Section 3 registrations, 524-581 and 68467-7, in July, 2009.

Currently, the majority of U.S. corn production utilizing PIP-containing corn requires a 20% non-insect protected (referred to as non-PIP or non-Bt) discrete structured refuge for insect-protected Bt corn. The majority of these products produce a single Bt toxin mode of action (insect control). The strategy to use two or more effective doses with differing modes of action (so-called pyramiding) as an effective way to combat resistance development is supported by academics and regulators as the most effective strategy to foster the durability of insect-protected biotech crops. SmartStax produces three *Bacillus thuringiensis* (Bt) protein toxins each with independent modes of action against lepidopteran corn pests, and two Bt protein toxins with independent modes of insect control against corn rootworms. Each insecticidal mode of action provides an effective dose against these pests. Thus, SmartStax represented a step-change in insect control and insect resistance management (IRM) for corn pests, providing multiple effective modes of action for the control of both above-ground lepidopteran pests and the below-ground corn rootworm (CRW) complex, enabling a significant reduction in the required refuge area (5%) in the U.S. Corn Belt compared with single toxin products (20%).

The IRM conditions of registration for SmartStax under registrations 524-581 and 68467-7 require growers in the U.S. Corn Belt (non-cotton growing areas) to plant 5% of their corn acres with a non-Bt common insect refuge for every 95% of their acres of SmartStax. The non-Bt 'common' refuge supports the production of non-resistant adult insects for both the lepidopteran and corn rootworm pests to mate with the respective surviving insects emerging from SmartStax plants, and thus serves as a refuge for both lepidopteran and corn rootworm pests. This non-Bt refuge corn can be placed as a discrete area, either as in-field strips, perimeter rows, adjacent block, or as a separate block within 1/2 mile from the SmartStax field. The specific refuge requirements are defined according to the prevailing pests in a given region, and whether plantings occur in major cotton growing regions.

Extensive laboratory and field studies, and conservative mathematical modeling, showed that even with the 5% structured refuge, the rate of resistance evolution should be at least three times slower for SmartStax than existing single toxin products utilized with a 20%

refuge. Given the significant improvements in insect control efficacy and spectrum, reduction in refuge, overall improvements in yields and potential for elimination of soil-applied pesticides, SmartStax corn has the potential to produce sizable pecuniary and non-pecuniary benefits for farmers and the environment. The multiple effective dose strategy is a central component of the durable IRM refuge strategy for SmartStax, using a 5% refuge in any field configuration.

Although the SmartStax registration provided data and modeling information to support deployment of various 5% discrete structured refuge option in the Corn Belt, Monsanto and Dow have investigated alternative refuge designs over many years. This includes an interspersed refuge approach (commonly referred to as a 'seed mix', or 'refuge in a bag'), in which a fixed amount of non-Bt seed would be included within each bag of SmartStax seed corn to create a interspersed distribution of non-Bt refuge plants among the SmartStax corn plants across a field. Seed mixes of Bt and non-Bt seed have been recognized as a possible insect resistance management (IRM) strategy for Bt crops for almost two decades because of the value of having an IRM strategy implemented by the technology provider rather than growers. This removes the issue of grower compliance with the IRM strategy and ensures that a refuge will be present within every Bt crop field. Benefits of an interspersed refuge via seed mixes from an IRM perspective include:

- Consistent percentage of non-Bt plants in every Bt field
- An interspersed in-field distribution of non-Bt plants will be particularly beneficial for very large fields
- Reduced probability of mating between Bt-resistant adults
- Appropriate choice of refuge hybrid ensured
- Identical management of Bt and refuge plants
- No additional insecticide use on refuge plants
- Higher adoption of pyramided varieties, increasing the durability of all Bt traits

A major hindrance to enabling the development and deployment of an interspersed refuge structure in the past has been the minimum 20% refuge size necessary to ensure durability (time to resistance development) of single dose products. In-field refuges above 5% caused unacceptable total field yield losses in an interspersed in-field refuge structure. With the development of SmartStax corn containing two- and three- effective insecticide modes of action against targeted pests, the substantial increase in durability supported a reduction in the refuge from 20% to 5%. The durability of SmartStax with a 5% refuge for both above-ground and below-ground pests also strongly supports a 5% interspersed in-field refuge structure, as delivered by planting a seed mix refuge.

The central need for an interspersed refuge – as with any refuge strategy, is that it supports sufficient populations of susceptible target insects while enabling mixing of these insects with any resistant insects surviving in Bt corn fields. Compared with a block refuge, the novel characteristic of a seed mix is the interspersed nature of Bt and non-Bt plants within in a field. This spatial distribution will enhance the mixing of adult insects coming from Bt and non-Bt plants, ensuring that any resistant insects surviving on Bt plants will

encounter susceptible insects coming from non-Bt plants, which will be beneficial for IRM. However, this spatial distribution of plants in a field also could increase the likelihood that larval insects may move between Bt and non-Bt plants because all non-Bt plants will have neighboring Bt plants. Thus, it is important to quantify the impacts of this larval movement on the refuge function within an interspersed refuge from a seed mix.

Specifically, two criteria need to be met to confirm that a 5% seed mix refuge is as effective as current refuge options for SmartStax. First, the seed mix should not lead to a biologically significant increase in sub-lethal exposure of larvae to the Bt toxins that could increase selection for Bt resistance. This could occur either through early instar larvae of the target pests moving from Bt plants to non-Bt plants after sub-lethal exposure, or by larvae moving from non-Bt to Bt plants as larger, more Bt-tolerant instars. Assessment of this issue requires examining the susceptibility of larvae of different ages to the proteins in SmartStax. Based on extensive data, the expectation is that the enhanced toxicity conferred by the multiple effective modes of action of SmartStax will make it unlikely that larvae will be able to move and survive in this way, particularly for the highly susceptible lepidopteran target pests. Second, the non-Bt plants in the interspersed field seed mix must support sufficient susceptible pest insects to be an adequate refuge. This can be assessed through direct surveys of pest population density on the non-Bt plants, together with appropriate mathematical modeling.

To this aim, this registration application provides data collected over the past three years assessing the efficacy and value of an interspersed 5% in-field refuge option, via a seed mix containing an admixture of 5% non-Bt refuge seed + 95% SmartStax seed, as an additional refuge strategy for SmartStax corn in the U.S. Corn Belt. Details of these data and analyses are presented in Volume 2 of this submission. The supporting data and information included in this request include (1) data on larval movement and survival in a 5% interspersed in-field refuge for the key lepidopteran (European corn borer (ECB) and southwestern corn borer (SWCB)) and coleopteran target pests (primarily western corn rootworm (WCR) and secondarily northern corn rootworm (NCR)); (2) mathematical modeling to demonstrate the acceptable risk of a interspersed 5% in-field refuge strategy compared to existing refuge strategies; (3) data on the efficacy of a 5% interspersed refuge against the target pests, and the impact of the non-Bt plants in the interspersed refuge on overall yield; (4) criteria are described for ensuring and verifying a consistent seed mix percentage during the manufacturing process; and additionally, (5) information outlining the benefits for growers, the public, and environment that would result from the addition of an interspersed refuge option for SmartStax (Volume 3 of this submission).

Presented in Volume 2, laboratory and field data indicate that a 5% seed mix will provide an effective refuge for SmartStax for ECB, SWCB, and the CRW species. For all of these pests, the non-Bt plants in a 5% seed mix consistently supported large populations of susceptible insects, while the SmartStax plants had few or no survivors. Highly conservative mathematical modeling shows that an interspersed refuge strategy will ensure the durability of SmartStax corn and will provide comparable or greater durability than 5% structured refuge in the Corn Belt, depending upon the nature of compliance with the structured refuge, and greater durability than single Bt products with a 20% refuge.

Furthermore, this approach will provide yields comparable to current structured refuge systems but with greater convenience and reduced insecticide use on the refuge, thereby bringing additional benefits beyond those of SmartStax with 5% discretely structured refuge.

Presented in Volume 3, the benefits to growers, the environment, and to society at large will be realized by the addition of an interspersed 5% in-field refuge option for SmartStax. Under all 5% refuge options (the strip or block refuge strategy supported in SmartStax registrations 524-581 and 68467-7, and the interspersed 5% in-field refuge proposed with this application), SmartStax represents significant value to U.S. farmers. There are unique benefits to a SmartStax 5% interspersed refuge above those provided by discrete strip or block refuges. These include substantial non-pecuniary grower benefits, environmental benefits, and improved compliance with IRM requirements. Enabling growers to broadly plant SmartStax corn with an interspersed in-field refuge will support:

- Reduction or potential elimination of application of soil-applied insecticides
- Reduce potential for corn rootworm insecticides in ground or surface water
- Reduce farm worker exposure to organophosphate insecticides, accidental insecticide spills, and insecticide carryover effects
- Increase simplicity, flexibility, and time savings associated with planting the refuge
- Guarantee grower compliance with IRM requirements
- Provide incentive to growers to switch to pyramided Bt technology, improving durability of Bt corn technology

This request for a registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax) will allow an in-field refuge structure in which the non-Bt refuge plants are interspersed within the SmartStax field. This type of interspersed in-field refuge would be implemented by growers planting a defined seed mixture comprised of PIP (SmartStax) seed with a fixed amount of non-Bt (refuge) seed. In addition, the interspersed refuge would only be implemented via planting a seed-mixture manufactured by the technology provider (registrants) and appropriately licensed seed producer affiliates. This non-Bt refuge would be complementary, but distinct from, the refuge structures currently allowed under SmartStax registrations 524-581 and 68467-7 (in-field strips, rows, or blocks).

The seed mix itself is not within scope of the EPA regulations for PIPs because this registration request (addition of unregulated non-PIP seed materials to PIP seed corn prior to planting) has not changed the underlying PIP (SmartStax). It is the plant incorporated protectant (pesticide) and associated genetic material within the plant that is regulated, not the plant itself of the seed mix, variety, or delivery mechanism of the seed into the field. This position has been previously clarified by the Agency. EPA has defined PIPs as "Pesticidal substances and the genetic material needed to produce them by plants that have been genetically modified so the plant is protected from certain insect pests. For example, scientists can take the gene for the Bt pesticidal protein from the bacterium, and introduce that gene into the plant's own genetic material. Then the plant manufactures the substance that destroys the pest. EPA regulates the protein and its genetic material, but not the plant itself..." <http://www.epa.gov/pesticides/ees/tool/decisiontree/main.htm> (accessed 11-30-

2009). Additionally, the scope of this registration request is only partially analogous to other registration requests involving corn seed mixtures of two different PIPs, whereas the scope of this present request involves a single PIP product that is currently registered (524-581 and 68467-7) for other in-field refuge arrangements. Thus, for this request, the in-field relationship of SmartStax to the non-PIP refuge does not change the composition of the SmartStax PIP (the pesticidal proteins and associated genetic material listed in the Confidential Statement of Formula). Additionally, the overall field composition of SmartStax with a 5% interspersed in-field refuge would be the same as that of a 5% in-field strip row refuge configuration allowed in registrations 524-581 and 68467-7. The IRM structure described herein does not involve the utilization of any additional PIPs or change to the confidential statement of formula (CSF) or label ingredients, but instead allows the currently mandated refuge in the field to be interspersed within the field as opposed to being placed in rows within or adjacent to the field. The mechanism of ensuring compliance with the interspersed refuge option is by limiting grower use of this option to planting seed mixes produced by the registrants and properly enabled, licensed seed producers.

In developing an IRM strategy for SmartStax using a structured refuge that is interspersed within the field, the data must address aspects related to proximity of the PIP and non-PIP plants, insect pest presence and biology, and productivity of adult insects from individual plants within the interspersed in-field refuge compared to other forms of structured refuges. The IRM properties of SmartStax, particularly the multiple effective modes of action against both above and below-ground pests, open the opportunity to add options for an interspersed in-field refuge to the current approved structured refuge options. Such an in-field option and the delivery of the option to growers as a seed mix would strengthen the existing IRM program by ensuring that a refuge is present in every SmartStax corn field deploying this option and removing concerns about grower compliance with refuge requirements. EPA has previously recognized that multiple refuge options for Bt corn and cotton products are essential to prevent the rapid onset of resistance. As additional data have been developed on IRM, EPA has granted registrants amended registrations to enhance farmers' refuge options and overall compliance. Currently, SmartStax corn non-Bt refuges can be planted as in-field four row strips, perimeters, in-field blocks, and separate blocks adjacent to the Bt field. Similarly, in the case of a dual effective mode of action cotton product like Bollgard II (MON 15985, EPA Reg. No. 524-522), either a structured refuge or a so-called natural refuge (no non-Bt cotton refuge), may be utilized. In all of these registration amendments, the principle goal was to ensure a strong IRM program. The EPA has ample precedence amending Bt crop registrations to allow for optimization of size, structure, or placement of the refuge structure in Bt crops, as well as different use instructions.

Therefore, Monsanto and Dow are hereby requesting a registration for the plant-incorporated protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) necessary for their production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration. The interspersed refuge would be implemented via a seed mixture in bags of seed corn

consisting of 5% non-Bt corn along with 95% SmartStax corn. Seed mixtures to be planted under this option would only be prepared by seed producers licensed by the registrants to ensure consistency and provide adequate refuge in the field. Studies and information supporting the request are provided in Volumes 1, 2, and 3 of this submission.

### SECTION III

#### PRODUCT LABEL

The subject of this application is for the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in corn (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 to allow an additional IRM interspersed in-field refuge configuration. This refuge configuration is enabled by a seed-mixture containing PIP and non-PIP seed, and is limited to use in the U.S. Corn Belt. Five copies of the proposed label for the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, to support an interspersed in-field refuge are attached.

Plant-Incorporated Protectant Label  
**MON 89034 × TC1507 × MON 88017 × DAS-59122-7**

Insect-Protected, Herbicide-Tolerant Corn  
(Alternate Brand Name Genuity™ SmartStax™)

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 ×  
MON-88017-3 × DAS-59122-7)

**Active Ingredients:**

*Bacillus thuringiensis* Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0026%\*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0053%\*

*Bacillus thuringiensis* Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507 .....≤ 0.0012%\*

*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....≤ 0.0079%\*

*Bacillus thuringiensis* Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7.....≤ 0.0194%\*

*Bacillus thuringiensis* Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7.....≤ 0.0042%\*

**Inert Ingredients:**

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017 .....≤ 0.0052%\*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17662 and PHP8999) for its production in corn event TC1507 and DAS-59122-7.....≤ 0.00045%\*

\*Maximum percent (wt/wt) of dry forage

**KEEP OUT OF REACH OF CHILDREN**

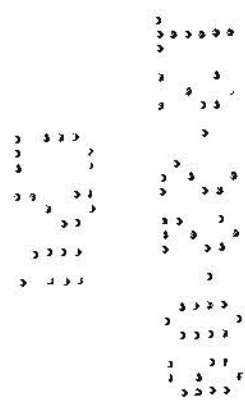
**CAUTION**

NET CONTENTS \_\_\_\_\_

EPA Registration No. 524-XXX  
EPA Establishment No. 524-MO-002

Monsanto Company  
800 North Lindbergh Blvd.  
St. Louis, MO 63167

0124  
0042  
0236



## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by a Grower/IRM Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products. A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product's refuge configuration is interspersed within the field and is allowed only by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed, and is limited to use in the U.S. Corn Belt.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn under this registration; however, seed propagation over 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year would utilize the discrete refuge options for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under EPA registration 524-581.

Ability to plant this interspersed refuge configuration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is based on geography and the insect pressure present in various locations. In non-cotton growing regions and in cotton growing regions where corn earworm is not a significant pest (i.e. the same regions where the minimum refuge size is 5% under Genuity™ SmartStax™ registration 524-581), a seed mix refuge option is allowed. Planting SmartStax corn in regions prohibiting an interspersed refuge option is still available to growers under registration 524-581. The interspersed refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 × TC1507 × MON 88017 × DAS-59122-7. The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each unit of seed corn.

The interspersed refuge option can only be used by planting seed corn specifically generated by seed producers licensed by the registrant. With this option, the refuge seed may not be treated with seed-applied insecticides for Corn Rootworm (CRW) control, and the refuge plants may not be treated with insecticides for Lepidopteran pest or CRW

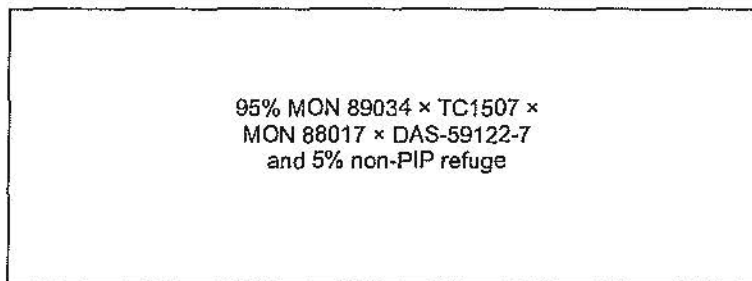
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control unless the entire field is treated. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

A schematic of the interspersed refuge from planting a seed mix of 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed with 5% non-PIP com is shown below. This option is not allowed in cotton-growing regions where corn earworm is a significant pest (i.e. the regions where the minimum refuge size is 20% under SmartStax registration 524-581).

#### Interspersed Refuge



The table below summarizes the interspersed refuge option for each region based on the planting of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed mixture in cotton or non-cotton growing regions and the insect pressure present in those locations.

Region	Planting Refuge as seed mix allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW, and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	No
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW, and MCRW are not significant: NM, AZ, CA, NV	Yes
Non-cotton growing where WCRW, NCRW, and MCRW are not significant: OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin	Yes

City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton)	
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### Corn Insects Controlled or Suppressed

European corn borer (ECB)	<i>Ostrinia nubilalis</i>
Southwestern corn borer (SWCB)	<i>Diatraea grandiosella</i>
Southern cornstalk borer (SCSB)	<i>Diatraea crambidoides</i>
Corn earworm (CEW)	<i>Helicoverpa zea</i>
Fall armyworm (FAW)	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Lesser corn stalk borer	<i>Elasmopalpus lignosellus</i>
Sugarcane borer (SCB)	<i>Diatraea saccharalis</i>
Western bean cutworm (WBC)	<i>Richia albicosta</i>
Black cutworm	<i>Agrotis ipsilon</i>
Western corn rootworm (WCRW)	<i>Diabrotica virgifera virgifera</i>
Northern corn rootworm (NCRW)	<i>Diabrotica barberi</i>
Mexican corn rootworm (MCRW)	<i>Diabrotica virgifera zeae</i>

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: \_\_/\_\_/\_\_

Plant-Incorporated Protectant Label  
**MON 89034 × TC1507 × MON 88017 × DAS-59122-7**

Insect-Protected, Herbicide-Tolerant Corn  
(Alternate Brand Name Genuity™ SmartStax™)

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 ×  
MON-88017-3 × DAS-59122-7)

**Active Ingredients:**

*Bacillus thuringiensis* Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0026%\*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0053%\*

*Bacillus thuringiensis* Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507 .....≤ 0.0012%\*

*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....≤ 0.0079%\*

*Bacillus thuringiensis* Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7 .....≤ 0.0194%\*

*Bacillus thuringiensis* Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7 .....≤ 0.0042%\*

**Inert Ingredients:**

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017 .....≤ 0.0052%\*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17662 and PHP8999) for its production in corn event TC1507 and DAS-59122-7.....≤ 0.00045%\*

\*Maximum percent (wt/wt) of dry forage

KEEP OUT OF REACH OF CHILDREN

## CAUTION

NET CONTENTS \_\_\_\_\_

EPA Registration No. 524-XXX

EPA Establishment No. 524-MO-002

Monsanto Company  
800 North Lindbergh Blvd.  
St. Louis, MO 63167

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by a Grower/IRM Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products. A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product's refuge configuration is interspersed within the field and is allowed only by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed, and is limited to use in the U.S. Corn Belt.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn under this registration; however, seed propagation over 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year would utilize the discrete refuge options for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under EPA registration 524-581.

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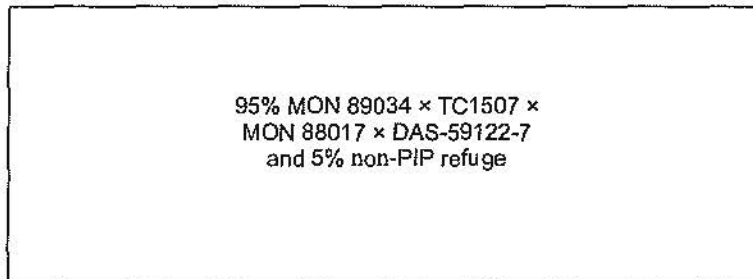
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A schematic of the interspersed refuge from planting a seed mix of 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed with 5% non-PIP corn is shown below. This option is not allowed in cotton-growing regions where corn earworm is a significant pest (i.e. the regions where the minimum refuge size is 20% under SmartStax registration 524-581).

#### Interspersed Refuge



The table below summarizes the interspersed refuge option for each region based on the planting of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed mixture in cotton or non-cotton growing regions and the insect pressure present in those locations.

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Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)	No
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### Corn Insects Controlled or Suppressed

European corn borer (ECB)	<i>Ostrinia nubilalis</i>
Southwestern corn borer (SWCB)	<i>Diatraea grandiosella</i>
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EPA Accepted: \_\_/\_\_/\_\_

Plant-Incorporated Protectant Label

**MON 89034 × TC1507 × MON 88017 × DAS-59122-7**

**Insect-Protected, Herbicide-Tolerant Corn  
(Alternate Brand Name Genuity™ SmartStax™)**

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 ×  
MON-88017-3 × DAS-59122-7)

**Active Ingredients:**

*Bacillus thuringiensis* Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0026%\*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0053%\*

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*Bacillus thuringiensis* Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7.....≤ 0.0042%\*

**Inert Ingredients:**

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017 .....≤ 0.0052%\*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17662 and PHP8999) for its production in corn event TC1507 and DAS-59122-7.....≤ 0.00045%\*

\*Maximum percent (wt/wt) of dry forage

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

NET CONTENTS \_\_\_\_\_

**EPA Registration No. 524-XXX**

**EPA Establishment No. 524-MO-002**

Monsanto Company  
800 North Lindbergh Blvd.  
St. Louis, MO 63167

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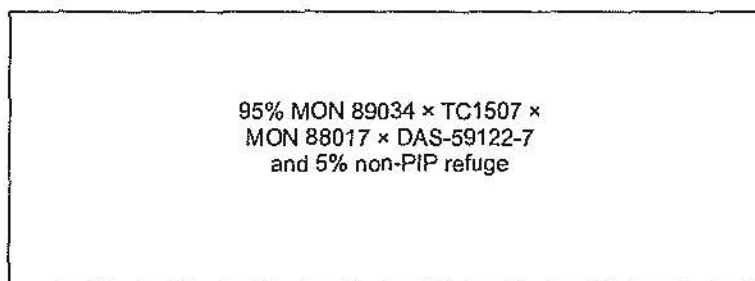
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#### Interspersed Refuge



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EPA Accepted: \_\_/\_\_/\_\_

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\*Maximum percent (wt/wt) of dry forage

KEEP OUT OF REACH OF CHILDREN

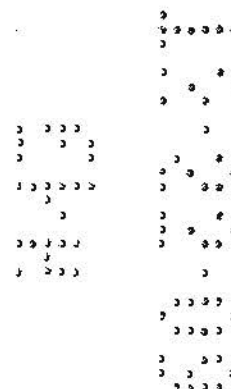
**CAUTION**

NET CONTENTS \_\_\_\_\_

EPA Registration No. 524-XXX

EPA Establishment No. 524-MO-002

Monsanto Company  
800 North Lindbergh Blvd.  
St. Louis, MO 63167



## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by a Grower/IRM Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products. A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product's refuge configuration is interspersed within the field and is allowed only by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed, and is limited to use in the U.S. Corn Belt.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn under this registration; however, seed propagation over 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year would utilize the discrete refuge options for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under EPA registration 524-581.

Ability to plant this interspersed refuge configuration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is based on geography and the insect pressure present in various locations. In non-cotton growing regions and in cotton growing regions where corn earworm is not a significant pest (i.e. the same regions where the minimum refuge size is 5% under Genuity™ SmartStax™ registration 524-581), a seed mix refuge option is allowed. Planting SmartStax corn in regions prohibiting an interspersed refuge option is still available to growers under registration 524-581. The interspersed refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 × TC1507 × MON 88017 × DAS-59122-7. The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each unit of seed corn.

The interspersed refuge option can only be used by planting seed corn specifically generated by seed producers licensed by the registrant. With this option, the refuge seed may not be treated with seed-applied insecticides for Corn Rootworm (CRW) control, and the refuge plants may not be treated with insecticides for Lepidopteran pest or CRW

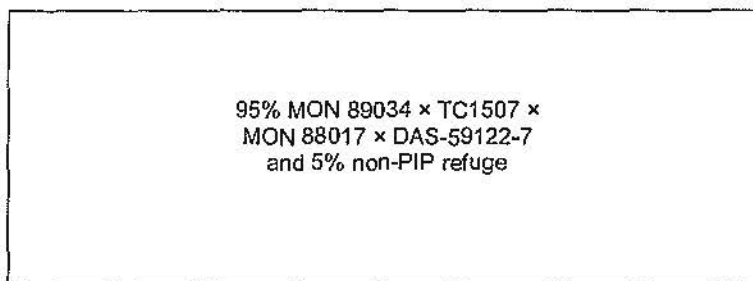
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control unless the entire field is treated. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

A schematic of the interspersed refuge from planting a seed mix of 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed with 5% non-PIP corn is shown below. This option is not allowed in cotton-growing regions where corn earworm is a significant pest (i.e. the regions where the minimum refuge size is 20% under SmartStax registration 524-581).

#### Interspersed Refuge



The table below summarizes the interspersed refuge option for each region based on the planting of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed mixture in cotton or non-cotton growing regions and the insect pressure present in those locations.

Region	Planting Refuge as seed mix allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW, and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	No
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW, and MCRW are not significant: NM, AZ, CA, NV	Yes
Non-cotton growing where WCRW, NCRW, and MCRW are not significant: OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin	Yes

City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton)	
Non-cotton growing where WCRW, NCRW, and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)	Yes

### Corn Insects Controlled or Suppressed

European corn borer (ECB)	<i>Ostrinia nubilalis</i>
Southwestern corn borer (SWCB)	<i>Diatraea grandiosella</i>
Southern cornstalk borer (SCSB)	<i>Diatraea crambidoides</i>
Corn earworm (CEW)	<i>Helicoverpa zea</i>
Fall armyworm (FAW)	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Lesser corn stalk borer	<i>Elasmopalpus lignosellus</i>
Sugarcane borer (SCB)	<i>Diatraea saccharalis</i>
Western bean cutworm (WBC)	<i>Richia albicosta</i>
Black cutworm	<i>Agrotis ipsilon</i>
Western corn rootworm (WCRW)	<i>Diabrotica virgifera virgifera</i>
Northern corn rootworm (NCRW)	<i>Diabrotica barberi</i>
Mexican corn rootworm (MCRW)	<i>Diabrotica virgifera zeae</i>

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: \_\_/\_\_/\_\_

Plant-Incorporated Protectant Label  
**MON 89034 × TC1507 × MON 88017 × DAS-59122-7**

Insect-Protected, Herbicide-Tolerant Corn  
(Alternate Brand Name Genuity™ SmartStax™)

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 ×  
MON-88017-3 × DAS-59122-7)

**Active Ingredients:**

*Bacillus thuringiensis* Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0026%\*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034.....≤ 0.0053%\*

*Bacillus thuringiensis* Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507 .....≤ 0.0012%\*

*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....≤ 0.0079%\*

*Bacillus thuringiensis* Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7 .....≤ 0.0194%\*

*Bacillus thuringiensis* Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7 .....≤ 0.0042%\*

**Inert Ingredients:**

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017 .....≤ 0.0052%\*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17662 and PHP8999) for its production in corn event TC1507 and DAS-59122-7.....≤ 0.00045%\*

\*Maximum percent (wt/wt) of dry forage

KEEP OUT OF REACH OF CHILDREN

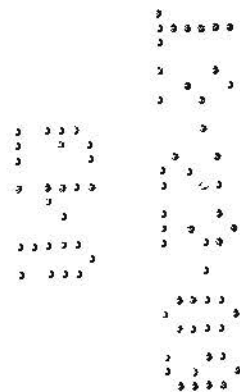
**CAUTION**

NET CONTENTS \_\_\_\_\_

EPA Registration No. 524-XXX

EPA Establishment No. 524-MO-002

Monsanto Company  
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St. Louis, MO 63167



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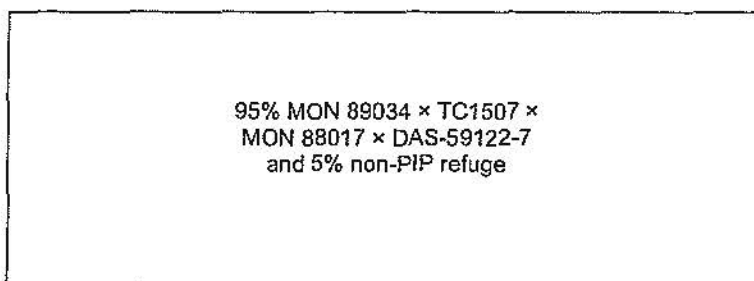
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City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton)	
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MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: \_\_/\_\_/\_\_

## SECTION IV

### PRODUCT ANALYSIS

Studies and volumes addressing product analysis were previously reviewed under EPA registration 524-581. These studies are referenced by MRID in the data matrix and describe the a) human health and environmental assessment of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, b) the molecular identity of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and c) levels of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins produced in tissues of MON 89034 × TC1507 × MON 88017 × DAS-59122-7.

## SECTION V

### RESIDUE DATA

EPA has registered the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, and Cry34/Cry35Ab1 proteins as produced in corn. The safety of these proteins has been demonstrated and they are exempted from the requirement of a tolerance.

Protein	Tolerance Exemption Information		
	40 CFR	Date	Crop(s)
Cry1A.105	§174.502	2008	Corn
Cry1F	§174.520	2001	Corn
Cry2Ab2	§174.519	2008	Corn and Cotton
Cry3Bb1	§174.518	2004	Corn
Cry34/ Cry35Ab1	§174.506	2005	Corn

## SECTION VI

### NONTARGET ORGANISM DATA

Studies conducted by Monsanto to characterize the potential hazards to non-target organisms (NTOs) as a result of exposure to the CryIA.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins have previously been submitted to EPA and were reviewed for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under registration 524-581, and are referenced by MRID in the data matrix.

## SECTION VII

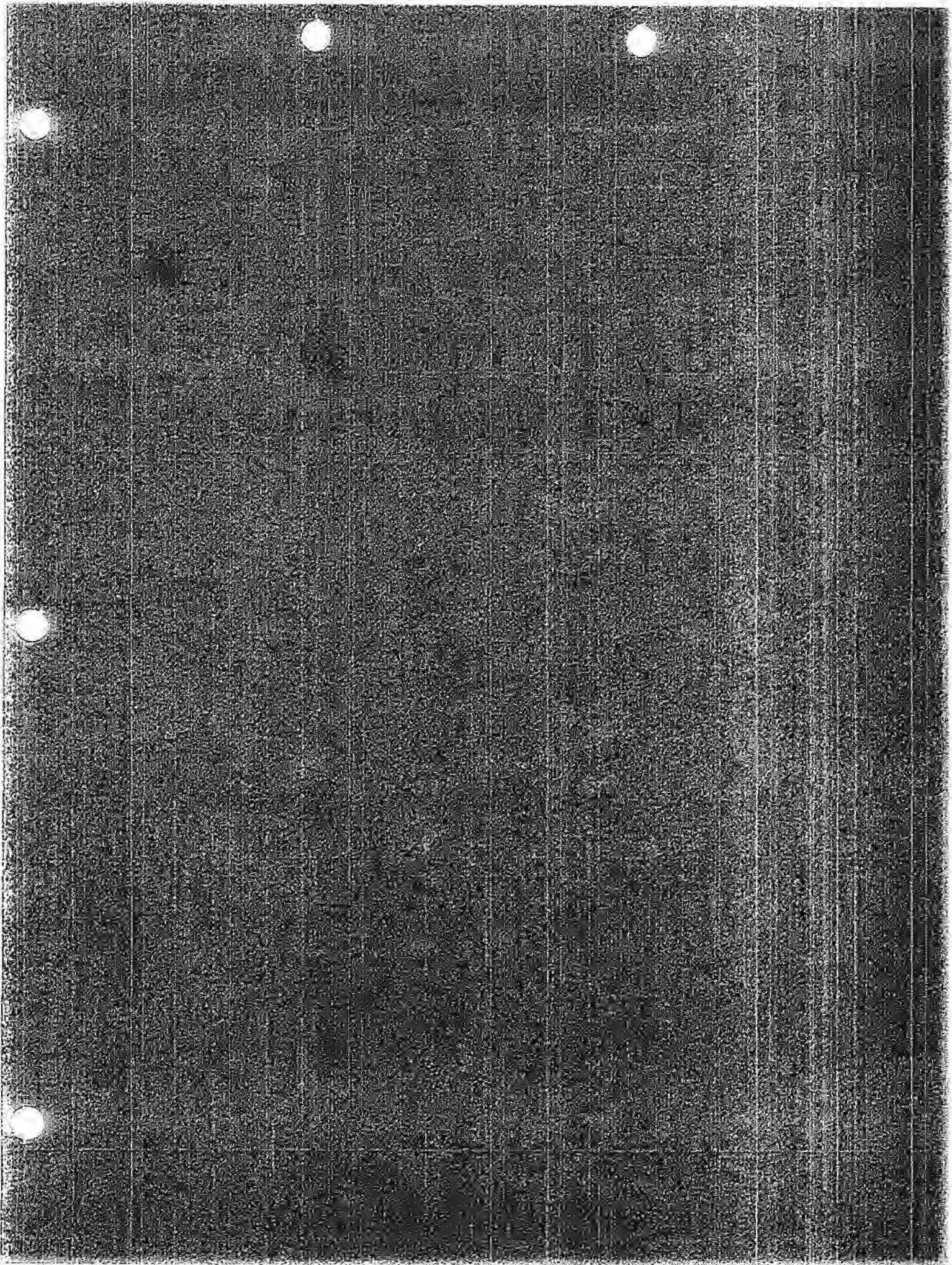
### TOXICOLOGY DATA

Studies conducted to assess the potential toxicity and allergenicity of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 and the inert proteins have previously been submitted to EPA and were reviewed for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under registration 524-581. These studies are referenced by MRID in the data matrix. Studies demonstrating functional equivalence of the *E. coli*- and plant-produced Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 PIP proteins have previously been submitted to EPA and are exempted from the requirement of a tolerance: 40 CFR §174.502, §174.519, §174.520, §174.518, and §174.506, and were reviewed for products TC1507, DAS-59122-7, MON 88017, MON 89034, and for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under registration 524-581. These studies are referenced by MRID number in the data matrix. The CP4 EPSPS and PAT proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 are classified as plant pesticide inert ingredients and are exempted from the requirement of a tolerance: 40 CFR §174.523 and §174.522, respectively, and the studies pertinent to those reviews are referenced by MRID number in the data matrix.

## SECTION VIII

### EFFICACY DATA

Studies and data demonstrating the efficacy and spectrum of insecticidal activity of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 were reviewed for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under registration 524-581, and are referenced by MRID in the data matrix. Data demonstrating the efficacy of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 relative to utilization of an interspersed in-field refuge is presented in Volume 2 of this submission.



[illegible]

1871  
1872

1. The first part of the document is a letter from the President of the United States to the Congress, dated January 1, 1861. It is a formal address, and it begins with the words "I have the honor to acknowledge the receipt of your letter of the 28th inst."

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12/22/09

SECRET

1. Definition of Terms and Abbreviations

1981

[illegible]

**Pages 615 - 624**

**\*Confidential Statement of Formula may be entitled to confidential treatment\***

# Ingredient Information

Ingredient Name: 5-Enolpyruvylshikimate-3-phosphate synthase from agrobacterium sp. strain CP4 (CP4 EPSPS) Other Systematic

PC Code: B17306

CAS:

Inert Ingredient? ☒ Yes ☐ No

First Registered: 18-Nov-1998

Food Use? ☒ Yes ☐ No

Active Ingredient? ☐ Yes ☒ No

Restricted Distribution? ☐ Yes ☒ No

RRCA #:

RRCA List:

RRCA Name:

Regeneration Case Status

FR Notices

Repository

Inert Mixture

Other IDs

Other CAS #

Assessment/Mode of Action

Cancer Class

Classification

Parent Ingredients

Child Ingredients

Ingredient Names

Pesticide Type

Pesticide Category

Pesticide Attributes

Ingredient Status

Comments

MSDS Information

Team Owner

Approved under 40 CFR 174.523 (previously 40 CFR 180.1174) CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase in all plants; exemption from the requirement of a tolerance. Residues of the CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase enzyme in all plants are exempt from the requirement of a tolerance when used as plant incorporated protectant inert ingredients in all food commodities. [Federal Register / Vol. 72, No. 79 / Wednesday, April 25, 2007 / Rules and Regulations / pp. 20431-20436] SR 12/3/2009

**\*Confidential Statement of Formula may be entitled to confidential treatment\***

# Ingredient Information

Ingredient Name: Phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production when produced in plants as a plant pesticide inert ingredient Other Common

PC Code: B17305 CAS:  Inert Ingredient? ☒ Yes ☐ No First Registered: 14-May-1996

Food Use? ☒ Yes ☐ No Active Ingredient? ☐ Yes ☒ No Restricted Distribution? ☐ Yes ☒ No

RRCA #:  RRCA List:  RRCA Name:

☒ Reregistration Case Status 
 ☒ FR Notices 
 ☒ Repository 
 ☒ Inert Mixture 
 ☒ Other IDs 
 ☒ Other CAS # 
 ☒ Assessment/Mode of Action 
 ☒ Cancer Class 
 ☒ Classification 
 ☒ Parent Ingredients 
 ☒ Child Ingredients 
 ☒ Ingredient Names 
 ☒ Pesticide Type 
 ☒ Pesticide Category 
 ☒ Pesticide Attributes 
 ☒ Ingredient Status

☒ Comments 
 ☒ MSDS Information 
 ☒ Team Owner

Approved under 40 CFR 174.522 (previously 40 CFR 180.1151) Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance. Residues of the Phosphinothricin Acetyltransferase (PAT) enzyme are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities. SR 12/3/2009  
 EPA Reg. No. 66736-R pc code created for Michael Mendelsohn

Ingredient Information								
Ingredient Name: Phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production when produced in plants as a plant pesticide inert ingredient		Other Common						
PG Code: 817305	CAS:	Inert Ingredient? <input checked="" type="radio"/> Yes <input type="radio"/> No						
Food Use? <input checked="" type="radio"/> Yes <input type="radio"/> No		First Registered: 14 May 1996						
Active Ingredient? <input type="radio"/> Yes <input checked="" type="radio"/> No		Restricted Distribution? <input type="radio"/> Yes <input checked="" type="radio"/> No						
RRCA #:	RRCA List:	RRCA Name:						
<div> <div>Comments</div> <div>MSDS Information</div> <div>Team Owner</div> </div>								
<div> <div>Reregistration Case Status</div> <div>FR Notices</div> <div>Repository</div> <div>Inert Mixture</div> <div>Other IDs</div> <div>Other CAS #</div> </div>								
<div> <div>Assessment Mode of Action</div> <div>Cancer Class</div> <div>Classification</div> <div>Parent Ingredients</div> <div>Child Ingredients</div> </div>								
<div> <div>Ingredient Names</div> <div>Pesticide Type</div> <div>Pesticide Category</div> <div>Pesticide Attributes</div> <div>Ingredient Status</div> </div>								
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